

## ENVIRONMENTAL PROTECTION AGENCY (EPA)

### Environmental Protection Agency

#### Statement of Priorities

#### OVERVIEW

The U.S. Environmental Protection Agency (EPA) is the leading Federal agency responsible for protecting human health and the environment. Since its creation in 1970, EPA has taken actions that have led to measurable improvements in air and water quality, significant reductions in solid and hazardous wastes, and limitations on the use of harmful chemicals and pesticides.

Specifically, EPA leads the nation's environmental science, research, education and assessment efforts by:

**Developing and enforcing regulations:** EPA works to develop and enforce regulations that implement environmental laws enacted by Congress. EPA is responsible for researching and setting national standards for a variety of environmental programs, and delegates to States and tribes the responsibility for issuing permits and for monitoring and enforcing compliance. Where national standards are not met, EPA can issue sanctions and take other steps to assist the states and tribes in reaching the desired levels of environmental quality.

**Offering financial assistance:** In recent years, between 40 and 50 percent of EPA's enacted budgets have provided direct support through grants to State environmental programs. EPA grants to States, non-profits and educational institutions support high-quality research that will improve the scientific basis for decisions on national environmental issues and help EPA achieve its goals.

- EPA provides research grants and graduate fellowships.
- The Agency supports environmental education projects that enhance the public's awareness, knowledge, and skills to make informed decisions that affect environmental quality.
- The Agency also offers information for State and local governments and small businesses on financing environmental services and projects.
- EPA also provides other financial assistance through programs as the Drinking Water State Revolving Fund, the Clean Water State Revolving Fund, and the Brownfields program.

**Performing environmental research:** At laboratories located throughout the

nation, the Agency works to assess environmental conditions and to identify, understand, and solve current and future environmental problems; integrate the work of scientific partners such as nations, private sector organizations, academia and other agencies; and provide leadership in addressing emerging environmental issues and in advancing the science and technology of risk assessment and risk management.

**Sponsoring voluntary partnerships and programs:** The Agency works through its headquarters and regional offices with over 10,000 industries, businesses, non-profit organizations, and state and local governments, on over 40 voluntary pollution prevention programs and energy conservation efforts. Partners set voluntary pollution-management goals; examples include conserving water and energy, minimizing greenhouse gases, slashing toxic emissions, re-using solid waste, controlling indoor air pollution, and getting a handle on pesticide risks. In return, EPA provides incentives like vital public recognition and access to emerging information.

**Furthering environmental education:** EPA advances educational efforts to develop an environmentally conscious and responsible public, and to inspire personal responsibility in caring for the environment.

To view the Agency's complete strategic plan and annual report, go to <http://www.epa.gov/ocfopage/plan/plan.htm>.

#### FOCUSING ON A BETTER WAY

EPA is focusing on finding a better way of environmental protection, one that can accelerate environmental progress. The existing system has served the nation well . . . but today's challenges are more complex. New approaches are needed that can help achieve goals more quickly and cost-effectively. EPA is relying on four cornerstones to finding a better way - Collaborative problem-solving, market incentives, new technology, and a focus on results.

**Collaborative problem-solving** is a way of achieving more with our collective resources - bringing all available expertise and resources to bear in solving problems. For example, EPA is collaborating with States and other partners in an effort to improve the Great Lakes and scaling up its National Environmental Performance Track Program. Performance Track is the flagship EPA voluntary program that recognizes and rewards top-performing

facilities representing all sizes of businesses from a variety of sectors. This program provides public recognition to these entities and offers regulatory, policy, and administrative incentives, such as a low priority for routine EPA inspections, extended on-site storage times for hazardous waste, and reduced reporting frequency under the Clean Air Act.

**Incentives** are the second cornerstone. Market-based approaches or other incentives can lead businesses, government agencies, and other organizations to do more than is required. These approaches provide a way to link environmental and economic interests so that doing more for the environment nets more for the bottom line. EPA is working to build more incentives into our programs and policies. For example, EPA is proposing to use market-based approaches to drastically reduce emissions of mercury, SOx and NOx.

**Technology** is the third cornerstone. To continue making progress, it is critical to harness the latest scientific, technological, and information capabilities for environmental gain. For example under our Technology for a Sustainable Environment (TSE) program, after a competition, we award grants to support fundamental and applied research related to pollution prevention in industrial processes and methodologies ultimately leading to a reduction in waste at the source. Under this program, as an alternative to organic or halogenated solvents, a CO2-based process was developed. The work was further supported with a Small Business Innovation Research grant and now a \$400 million commercial facility is being built to exploit it.

**Focus on results** is the fourth cornerstone. EPA understands that traditional environmental strategies have sometimes gotten bogged down in process at the expense of real progress. One of the best examples is reducing dirty emissions from older diesel school buses. Recognizing diesel engines have long life spans - sometimes 30 years - and that many school systems would use current buses until they had "run their course," EPA launched a nationwide campaign to retrofit older buses and provide our children with a much cleaner, healthier ride to school. Hundreds of communities now have retrofitting programs underway.

EPA believes these cornerstones will be the foundation to finding a better way to environmental progress.

Attention to Small Businesses

Helping small businesses improve environmental performance is a top priority for EPA. EPA offers a variety of services for small businesses, including a toll-free hotline, a semiannual newsletter, online expert systems, and for some sectors, compliance assistance centers that focus on the unique environmental management issues facing specific industries. EPA also maintains a Small Business Ombudsman, which provides a point of contact for small businesses and ensures compliance with the Small Business Paperwork Relief Act of 2002.

In FY 2004, EPA is focusing on implementing the Small Business Strategy. By better coordinating small business activities, EPA aims to improve its technical assistance and outreach efforts, minimize burdens to small businesses in its regulations, and simplify small businesses' participation in its voluntary programs.

A number of rules included in this Plan may be of particular interest to small businesses (and for a more extensive list of rules affecting small businesses, please see appendices B and C to the Regulatory Agenda which is available at [epa.gov/regagenda](http://epa.gov/regagenda).)

- Groundwater Rule (2040-AA97)
- Long Term 2 Enhanced Surface Water Treatment Rule (2040-AD37)
- Stage 2 Disinfection Byproducts Rule (2040-AD38)
- Minimizing Adverse Environmental Impacts from Cooling Water Intake Structures (316(b) Phase III) Rule (2040-AD70)
- Standardized Permit for RCRA Hazardous Waste Management Facilities Final Rule (2050-AE44)
- Office of Solid Waste Burden Reduction Project Final Rule (2050-AE51)
- Recycling of Cathode Ray Tubes and Mercury-Containing Equipment: Changes to Hazardous Waste Regulations Final Rule (2050-AE52)
- Increase Metals Reclamation from F006 Waste Streams Proposed Rule (2050-AE97)
- Standards and Practices for Conducting "All Appropriate Inquiry" Proposed Rule (2050-AF04)
- Control of Emissions from Spark-Ignition Engines and Fuel Systems from Marine Vessels and Small Equipment (2060-AM34)

## HIGHLIGHTS OF EPA'S REGULATORY PLAN

### Office of Air and Radiation

The principal regulatory priority of EPA's Office of Air and Radiation (OAR) for FY 2005 is to protect public health and the environment from the harmful effects of fine particulate matter and ozone, the two air pollutants that persist widely in the Nation's air in amounts that exceed Clean Air Act health standards. Exposure to these pollutants is associated with numerous harmful effects on human health, including respiratory problems, heart and lung disease, and premature death. These pollutants also degrade visibility in National parks and other scenic areas. In addition to ozone and particulate pollution, OAR is continuing to address toxic air pollution by implementing a toxics-control program under the Clean Air Act. OAR is also working to increase the effectiveness and efficiency of its permitting programs, which are the main mechanisms through which these protections are implemented. These efforts are described briefly below.

One of OAR's principal vehicles to mitigate particulate and ozone pollution is the Clean Air Interstate Rule, which will achieve large reductions in sulfur dioxide and nitrogen oxide emissions that cause particulate and ozone pollution. Emissions of sulfur dioxide and nitrogen oxide, especially from electric powerplants, can be transported on the wind over long distances from the Midwest to the east coast. Such emissions can be a major factor in the pollution problems of eastern cities. This program will achieve its reductions through use of a "cap-and-trade" system similar to the one that has proved so successful in EPA's Acid Rain program. OAR is also developing a separate rule to enhance scenic areas by reducing the particulate pollution that restricts visibility in those areas.

OAR is also developing a rulemaking addressing another category of emissions that cause particulate and ozone pollution: emissions from locomotives and smaller marine engines. This rule will enhance the overall mobile-source control program that has already set stringent standards for most categories of vehicles, engines, and their fuels.

Even though these Federal rules will go a long way toward reducing the ozone and particulate pollution in America's cities, they can't do the job alone. Additional State and local control programs under the Clean Air Act will need to be instituted or enhanced in

many of the most polluted areas. To help and guide the States and local governments in these efforts, EPA is developing implementation rulemakings for both ozone and particulates that will provide technical help and policy guidance crucial to assuring that State and local efforts achieve their pollution-control goals.

OAR also continues to assess new scientific information that underlies the National Ambient Air Quality Standards (NAAQS), which are the centerpiece of the Clean Air Act and the foundation of OAR's program. In 2005, EPA expects to announce the results of the latest review of the particulate matter NAAQS in the form of a proposed rule to either revise or reaffirm the current standard.

EPA continues to address toxic air pollution under authority of the Clean Air Act Amendments of 1990. EPA has largely completed implementing the "Maximum Achievable Control Technology" (MACT) program, which has the goal of controlling toxic air pollution from major emitters nationwide. Toxic air pollution is a term that covers a large number of industrial chemicals and other substances that have been shown to cause cancer, birth defects, and developmental problems in children. To date, EPA's air toxics program has focused primarily on reducing emissions from large industrial sources, such as petroleum refineries and chemical manufacturing plants, through technology-based standards. When fully implemented, the overall MACT program will reduce more than one million tons of toxic air emissions per year. The Electric Utility MACT regulation will address one of the most significant remaining sources of mercury in the United States. While working on these standards, OAR is beginning to evaluate those sources with standards already in place to determine if the remaining risk from those sources warrants additional regulation.

Since many air quality programs are administered through permitting programs, OAR continues to work toward improving these programs to increase efficiency and reduce regulatory burden. Currently, OAR is developing rulemakings to streamline and improve its New Source Review (NSR) permitting program. This effort will clarify the circumstances under which companies must obtain construction permits before building new facilities or significantly modifying existing facilities. These revisions will provide more regulatory certainty by clarifying compliance requirements, and will also make the program easier to

administer while maintaining its environmental benefits. In developing these NSR rule revisions, OAR is drawing upon many years of intense involvement with major stakeholders, who have helped shape a suite of reforms that are expected to both improve the environmental effectiveness of these programs and make them easier to comply with.

The annual report on the costs and benefits of regulations, entitled "Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities," that is prepared by the Office of Management and Budget (OMB) and submitted to Congress each year, included several nominations for reform from the public. In FY2005, OAR expects to address through regulatory action one of the areas raised: New Source Review (Comments #16, 30, 77, 187, 188, 189, and 196). (For a copy of these comments, go to OMB's compilation of the comments at [http://www.whitehouse.gov/omb/inforeg/key\\_comments.html](http://www.whitehouse.gov/omb/inforeg/key_comments.html).)

#### Office of Environmental Information

EPA's Office of Environmental Information (OEI) continues to ensure that EPA collects and provides access to high quality environmental information and data to our partners, stakeholders, and the public. In keeping with this mandate, one of OEI's top regulatory priorities will be the finalization of the electronic reporting provisions of the Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR). EPA is deferring any further action on the CROMERRR electronic record-keeping provisions until a later time. This final rule will address electronic reporting by companies regulated under all of EPA's programs: air, water, pesticides, toxic substances, wastes, and emergency response. CROMERRR would remove existing regulatory obstacles to electronic reporting, and it would set requirements for companies choosing to report electronically. In addition, this rule would set the conditions for allowing electronic reporting under State, tribal, or local environmental programs that operate under EPA authorization.

CROMERRR is intended to make electronic reporting as simple, efficient, and cost-effective as possible for regulated companies, while ensuring that a transition from paper to electronic reporting does not compromise EPA's compliance and enforcement programs. Consequently, the Agency's strategy is to impose as few specific requirements

as possible, and to keep those requirements neutral with respect to technology, so the rule will pose no obstacles to adopting new technologies as they emerge.

To ensure that authorized programs at the State, tribal, and local levels meet CROMERRR's goals, the rule would specify a set of criteria that these programs must satisfy as they initiate electronic reporting. The final rule would specify a process for certifying that these programs meet the criteria. EPA is on schedule to finalize CROMERRR by the first half of FY2005. In response to public comment, a decision was made to focus the final rule on electronic reporting only, and to defer coverage of electronic record keeping until a later time. Also in response to comments, EPA currently is exploring a streamlined process to review State programs for electronic reporting.

Another key regulatory priority that OEI is undertaking is the enactment of burden reduction for the Toxics Release Inventory (TRI) reporting community. The TRI program collects chemical release and other waste management data on over 650 chemicals from over 24,000 facilities across the U.S. each year. To provide TRI reporters with appropriate burden relief, TRI intends to propose two rulemakings to address both short-term and longer-term reporting requirement modifications while maintaining the practical utility of the TRI data. Specifically, OEI intends to propose the TRI Reporting Forms Modification rule to address noncontroversial modifications to the TRI reporting requirements (i.e., Form R). At the same time, OEI intends to continue parallel work on a second rulemaking to examine more significant reporting modifications with greater potential impact on reporting burden. The second rulemaking, the "Toxics Release Inventory Reporting Burden Reduction Rule," focuses on exploring long-term reporting modifications.

OEI is assessing a number of burden reduction options for both rulemakings within the criteria of what is technically, practically and legally feasible in order to meet the goals and statutory obligations set forth for TRI reporting. Although the primary goal of both efforts is to reduce burden associated with TRI reporting, these rules will also maintain EPA's commitment to providing valuable information to the public.

In addition, EPA is committed to providing electronic means to its stakeholders to meet EPA's reporting

requirements, specifically through the Central Data Exchange (CDX) system. CDX is an integrated system that provides electronic reporting services to more than 30,000 users for 16 data flows in six major EPA media programs, and is on track to provide electronic reporting services for all significant environmental data collections over the next two years. By enabling the regulated community to utilize CDX as a reporting tool, the TRI Program has seen a 49% increase in the number of reports submitted to EPA via the Internet for TRI Reporting Year 2003 when compared to Reporting Year 2002. To take advantage of CDX's paperless reporting feature, TRI reporters must use the EPA-provided TRI Made-Easy (TRI-ME) Software. This upward trend toward greater Internet reporting via CDX is great news for the TRI program. Money saved from processing more-costly hard-copy paper submissions to TRI can now be reinvested in helpful tools and automated data quality checks to assist facilities and in ways to provide greater electronic means of accessing TRI data.

CDX also promulgated a number of new data flows, including the Office of Water's Stormwater Electronic Notice of Intent (an electronic permit application), the Office of Solid Waste and Emergency Response's Risk Management Plan WebRC (electronic updates of emergency contact information), and the Office of Prevention, Pesticides, and Toxic Substances' Lead Request for Certification (payment transactions online).

CDX is EPA's point of presence on the Environmental Exchange Network, known as the "Node." Using CDX, EPA has worked with States to provide the technical specifications and exchange protocols for the Network. CDX provides support services, including node building, security and authentication and help desk. OEI is working with the major programs to deploy their data flows as "node" exchanges, using XML and web services. These efforts are some examples of EPA's commitment to the collection and dissemination of the highest quality of environmental information.

#### Office of Prevention, Pesticides, and Toxic Substances

EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) plays an important role in protecting public health and the environment from potential risk from pesticides and chemicals. In addition to the daily

activities related to our licensing programs, OPPTS has identified several regulatory priorities for the coming year.

Evidence suggests that environmental exposure to man-made chemicals that mimic hormones (endocrine disruptors) may cause adverse health effects in human and wildlife populations. The Food Quality Protection Act directed EPA to develop a chemical screening program (the Endocrine Disruptor Screening Program, EDSP), using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have hormonal effects in humans. OPPTS is implementing recommendations from a scientific advisory committee, which was established to advise EPA on the EDSP, by developing and validating test systems for determining whether a chemical may have effects similar to those produced by naturally occurring hormones. As part of this program EPA is also designing a regulatory framework for procedures and processes to use when implementing the EDSP, and will develop an initial list of chemicals for which testing will be required. In early 2005, EPA anticipates publishing the final chemical selection approach for this initial list of chemicals, which was proposed in December 2002 for public comment.

In 2005, OPPTS will be revising its pesticide emergency exemption program, under which States and other Federal agencies may obtain permission to temporarily use a pesticide not in accordance with registration requirements under emergency conditions. In response to State concerns, EPA has already reduced the review time for emergency exemptions significantly. Other changes that EPA is considering have the potential for further streamlining the exemption program and allowing more flexibility in its applicability.

OPPTS will propose to update and revise data requirements for the registration of pesticide products in 40 CFR part 158. The regulations specify the data required as the basis for the Agency's pesticide risk assessment and licensing decisions. Although the Agency has kept pace with evolving scientific understanding of pesticide risks by requiring the submission of data on a case-by-case basis, the 1984 regulations have not been updated to reflect these data needs on a routine basis. The first in a series of proposals will address data requirements for conventional chemical pesticides for agricultural uses. Subsequent proposals

are planned for antimicrobial, biochemical, microbial pesticides, and plant-incorporated protectants.

In 2006, OPPTS will begin implementing a program, mandated by section 3(g) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), to review the registrations of all pesticides at least once each 15 years. The registration review program will replace the tolerance reassessment program (ending in 2006) and reregistration program (ending in 2008) currently underway. These two programs are both one-time reviews that evaluate and manage the risks posed by existing pesticides. The Agency intends to initiate registration review while it completes tolerance reassessment and reregistration. FIFRA 3(g) requires the Agency to establish procedural regulations for the registration review program. Promulgation of a procedural regulation is a very high priority for OPP, in order to achieve a smooth transition into the new registration review program.

EPA anticipates it will develop a policy or regulation concerning the use of human research to support Agency actions to protect public health and the environment. In developing a future policy or rule, EPA will consider the public comments received in response to the Advance Notice of Proposed Rulemaking issued in May 2003, and will also carefully consider advice from the National Academy of Sciences submitted to EPA in February 2004. The policy or rule would establish rigorous scientific and ethical standards that EPA would apply in its analysis of various types of research involving people exposed to toxicants to identify or quantify their effects. The Agency will particularly focus on "third-party intentional dosing human studies," but recognizes that standards applicable to these studies may also be applicable to other types of studies. "Third-party studies" refers to research not conducted or supported by EPA or other federal agencies, and therefore not governed by the regulation for "Protection of Human Subjects," widely referred to as the "Common Rule" (40 CFR part 26).

The Agency launched the HPV Initiative in April 1998 to collect or, where necessary, develop basic screening level hazard data necessary to provide critical information about the environmental fate and potential hazards associated with high production volume (HPV) chemicals. These chemicals are defined as organic chemicals manufactured (including

imported) at or above 1 million pounds per year based on information submitted under the 1990 Inventory Update Rule established pursuant to the Toxic Substances Control Act (TSCA). Data collected and/or developed under the HPV Initiative will provide critical basic information about the environmental fate and potential hazards associated with these chemicals which, when combined with information about exposure and uses, will allow the Agency and others to evaluate and prioritize potential health and environmental effects and take appropriate follow up action. The HPV Initiative includes a voluntary component, the HPV Challenge Program, and rulemaking under TSCA. Under the voluntary HPV Challenge Program component, EPA received commitments from 401 companies individually or through consortia and the International Council of Chemical Associations (ICCA) to sponsor 2,222 of the estimated 2,800 HPV chemicals included in the HPV Initiative. OPPTS issued a status report for the HPV Challenge Program on December 1, 2004. The report, "Status and Future Directions of the HPV Challenge Program," showcases the extensive voluntary participation by companies that have agreed to provide data to EPA on chemicals they manufacture or import, and outlines a preliminary strategy for how EPA will deal with chemicals that are not yet sponsored. More information about the report and the HPV Chemical Program is available at <http://www.epa.gov/chemrtk/hpvstatr.htm>.

In the spring of 2005, OPPTS expects to issue a final rulemaking under TSCA that will require testing for a number of the HPV chemicals that were not sponsored as part of the voluntary HPV Challenge Program.

Childhood lead poisoning is an ongoing problem in the United States, with almost a million young children having more than 10 ug/dl of lead in their blood (Center for Disease Control's level of concern). Although there have been dramatic declines in blood-lead levels due to reductions of lead in paint, gasoline and various food sources, remaining lead-based paint in older houses continues to be a significant source of childhood lead poisoning. Section 402(c) of TSCA directs EPA to address renovation and remodeling activities in these older houses by first conducting a study of the extent to which persons engaged in various types of renovation and remodeling activities

are exposed to lead in the conduct of such activities or disturb lead and create a lead-based paint hazard on a regular basis. Section 402(c) further directs the Agency to revise the lead-based paint activities regulations (40 CFR part 745 Subpart L) to include renovation or remodeling activities that create lead-based paint hazards. In order to determine which contractors are engaged in such activities the Agency is directed to utilize the results of the study and consult with the representatives of labor organizations, lead-based paint activities contractors, persons engaged in remodeling and renovation, experts in health effects, and others. Given the significant number of older houses affected, such a rule is likely to have a potentially significant economic impact. In an effort to minimize that impact, the Agency has worked with stakeholders to explore the development of non-regulatory approaches for reducing the potential creation of lead-based paint hazards from renovation or remodeling activities. The Agency will be pilot testing one such approach, the "Lead Safety Partnership," beginning in the fall of 2004. The Lead Safety Partnership is a public/private initiative to encourage contractors to use Lead Safe Work Practices (LSWP) during renovation, repair, and painting. LSWP are a set of work methods that avoid making and spreading lead-contaminated dust. Such lead-based paint program activities are intended to insure that the individuals and firms conducting lead-based paint activities will do so in a way that safeguards the environment and protects the health of building occupants, especially children under six years old.

In 2005, OPPT expects to assess the status of the pending implementation in the U.S. of the Rotterdam Convention on Prior Informed Consent (PIC), which includes export notification requirements related to a comment mentioned in OMB's 2002 Report to Congress on the Costs and Benefits of Regulations. (See OMB's compilation of comments, summary no. 190, page 10, commenter no. 12 available at [http://www.whitehouse.gov/omb/inforeg/key\\_comments.html](http://www.whitehouse.gov/omb/inforeg/key_comments.html).)

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#### Office of Solid Waste and Emergency Response

The Office of Solid Waste and Emergency Response (OSWER) has a number of regulatory priorities aimed at improving environmental quality. Protection of public health and the environment and environmental stewardship are two key themes, as is reducing burden on the regulated community where environmental protections are maintained.

EPA will promote and protect air quality by reducing emissions of arsenic, beryllium, cadmium, chromium, dioxins and furans, hydrogen chloride, lead, manganese, and mercury, all of which cause adverse health effects. EPA plans to promulgate national emission standards for these hazardous air pollutants for hazardous waste combustors. This rule will also contain a final decision to the Cement Kiln Recycling Coalition petition of the Administrator to withdraw Agency policy and technical guidance concerning site-specific risk assessments for hazardous waste combustors and re-issue them as regulations, if EPA continues to believe that they are necessary. This rule also

supports a reform nomination for site-specific risk assessments in the Resource Conservation and Recovery Act (RCRA) that was mentioned in OMB's 2002 Report to Congress on the Costs and Benefits of Regulations.

To promote environmental stewardship, EPA is encouraging recycling. One of the largest hazardous waste streams amenable to recycling is the wastewater treatment sludges from electroplating operations (waste code F006). EPA is considering changes to the existing RCRA regulations to encourage safe recycling and waste management practices of wastewater treatment sludges from electroplating operations. These electroplating sludges are sufficiently high in metal(s) and sufficiently low in other toxic constituents.

EPA also seeks to remove unnecessary regulatory barriers to recycling of Cathode Ray Tubes. These tubes, which are found in televisions and computer monitors, contain lead to protect users from x-rays. To promote recycling, EPA will seek to streamline RCRA requirements for managing mercury-containing equipment.

To reduce burden on the regulated community, Agency efforts are underway to eliminate duplicative and non-essential paperwork burden imposed by RCRA reporting and recordkeeping requirements. This rule will eliminate or streamline paperwork requirements that are unnecessary because they add little to the protectiveness of the RCRA regulations. This rule also supports a reform nomination for burden reduction under RCRA that was mentioned in OMB's 2002 Report to Congress on the Costs and Benefits of Regulations.

EPA also intends to reduce burden on the regulated community by revising the current RCRA regulations that apply to the wastewater treatment sludges from the chemical conversion coating (zinc phosphating) of aluminum. The current federal regulations require that the wastewater treatment sludges generated from this conversion coating process be managed as a RCRA hazardous waste. Yet, such sludges do not contain the constituents for which the F019 hazardous waste was originally listed (cyanide and chromium).

EPA also plans to streamline both the RCRA permit and hazardous waste manifest processes. The Agency is creating a standardized permit for RCRA facilities that generate hazardous waste and routinely manage the waste on-site in tanks, containers, and containment

buildings. This standardized permit process would allow facilities to obtain and modify permits more easily while maintaining the protectiveness currently existing in the individual RCRA permit process.

Likewise, the Agency plans to reduce paperwork burden by standardizing the Uniform Hazardous Waste Manifest, which is a multi-copy form used to identify the quantity, composition, origin, routing, and destination of RCRA hazardous waste during its transportation. EPA plans to specify one format for the manifests that may be used in all states. EPA is working toward standard requirements for tracking rejected wastes, container residues, and international shipments of hazardous wastes.

#### Office of Water

EPA's Office of Water's primary goals are to ensure that drinking water is safe, restore and maintain oceans, watersheds, and their aquatic ecosystems to protect human health, support economic and recreational activities, and provide healthy habitat for fish, plants, and wildlife. In order to meet these goals, EPA has established a number of regulatory priorities for the coming year. They include rules affecting cooling water intakes and drinking water.

In November 2004, EPA issued a proposed rule to control the adverse environmental impacts associated with cooling water intakes. Many power plants and factories withdraw large volumes of water from rivers, lakes, or other water bodies to cool their production equipment. As required by the Clean Water Act (CWA), EPA must ensure that the location, design, construction and capacity of these cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. EPA's rulemaking may affect existing facilities that use cooling water intake structures, and whose intake flow levels exceed a minimum threshold to be determined by EPA during this rulemaking. EPA will accept comments on the proposed rule until March 24, 2005.

Finally, EPA is developing three rules to protect the safety of drinking water. First, EPA is developing a final Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR). This rule would reduce risks from microbial pathogens, especially *Cryptosporidium*, in public water systems that use surface water sources. LT2ESWTR provisions would target systems where current

standards do not provide sufficient protection, including both filtered systems with elevated source water pathogen levels and unfiltered systems. Second, EPA plans to finalize the Ground Water Rule, a rule that addresses fecal contamination in public water systems served by ground water sources. Finally, EPA is developing a final Stage 2 Disinfectants and Disinfection Byproducts Rule to control exposure to disinfection byproducts beyond the requirements of the Stage 1 Disinfectants and Disinfection Byproducts Rule. This rule will respond to new data the Agency has received on: disinfection byproduct occurrence; bladder, colon, and rectal cancer; and possible reproductive and developmental health effects.

#### EPA

### PRERULE STAGE

#### 115. ENDOCRINE DISRUPTOR SCREENING PROGRAM (EDSP); CHEMICAL SELECTION APPROACH FOR INITIAL ROUND OF SCREENING

##### Priority:

Other Significant

##### Legal Authority:

15 USC 2603 TSCA; 21 USC 346(a) FFDCA; 42 USC 300(a)(17) SDWA; 7 USC 136 FIFRA

##### CFR Citation:

Not Yet Determined

##### Legal Deadline:

None

##### Abstract:

EPA published a proposed policy statement in the Federal Register setting forth the Endocrine Disruptor Screening Program (EDSP) on December 28, 1998. In that FR Notice, the Agency described the major elements of the Program EPA had developed to comply with the requirements of FFDCA section 408(p) as amended by FQPA. One of those elements is Priority Setting which was defined as the collection, evaluation, and analysis of relevant information to determine the general order in which chemical substances and mixtures will be subjected to screening and testing. Under this current action, EPA is developing a priority setting approach to be used by the Agency to identify the initial list of chemicals for which EDSP Tier 1 testing will be required.

On December 30, 2002, EPA published in the Federal Register for public comment a proposed chemical selection approach for this initial list of chemicals. The public comment period on this proposed approach was extended to April 1, 2003 in a Federal Register notice dated February 26, 2003. EPA has considered the comments and will issue a Federal Register notice setting forth its final approach. EPA will issue an additional Federal Register notice setting forth the draft initial list of chemicals it proposes for testing. This additional notice is expected to be published to allow sufficient time for review and comment prior to actual Tier 1 assay testing. Although this action is not a rulemaking, the Agency has included it in the Regulatory Agenda to help inform the public.

#### Statement of Need:

The Endocrine Disruptor Screening Program fulfills the statutory requirement to screen pesticide chemicals for their potential to disrupt the endocrine system and adversely affect human health.

#### Summary of Legal Basis:

The mandate to screen pesticide chemicals for estrogenic effects that may affect human health is section 408(p) of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a(p)). Discretionary authority to test contaminants in sources of drinking water is in the Safe Drinking Water Act as amended in 1996 (42 U.S.C. 300j-17). General authority to require testing of chemicals and pesticides is in TSCA (15 U.S.C. 2603) and FIFRA (7 U.S.C. 136) respectively.

#### Alternatives:

A federal role is mandated under cited authority. There is no alternative to the role of the Federal government on this issue to ensure that pesticides, commercial chemicals and contaminants are screened and tested for endocrine disruption potential. A limited amount of testing may be conducted voluntarily but this will fall far short of the systematic screening which is necessary to protect public health and the environment and ensure the public that all important substances have been adequately evaluated.

#### Anticipated Cost and Benefits:

None.

#### Risks:

Evidence is continuing to mount that wildlife and humans may be at risk

from exposure to chemicals operating through an endocrine mediated pathway. Preliminary studies show decreases on IQ tests and increases in aggression in children. Severe malformations of the genitals of boys has increased steadily over the last two decades and fertility has decreased in young males. Wildlife effects have been more thoroughly documented. Abnormalities in birds, marine mammals, fish, amphibians, alligators, and shellfish have been documented in the U.S., Europe, Japan, Canada, and Australia which have been linked to specific chemical exposures. Evidence is sufficient for the U.S. to proceed on a two track strategy: research on the basic science regarding endocrine disruption and screening with validated assays to identify which chemicals are capable of interacting with the endocrine system. The combination of research and test data submitted in this program will enable EPA to take action to reduce risks.

**Timetable:**

Action	Date	FR Cite
Notice: Proposed Approach	12/30/02	67 FR 79611
Notice: Final Approach	04/00/05	

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**Additional Information:**

SAN No. 4727, EDocket No. OPPT-2004-0109; Split from RIN 2070-AD26.

**URL For More Information:**

<http://www.epa.gov/scipoly/oscpendo/prioritysetting/index.htm>

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**RIN:** 2070-AD59

**EPA****116. NOTIFICATION OF CHEMICAL EXPORTS UNDER TSCA SECTION 12(B)****Priority:**

Other Significant

**Legal Authority:**

15 USC 2611

**CFR Citation:**

40 CFR 707

**Legal Deadline:**

None

**Abstract:**

Section 12(b)(2) of the Toxic Substances Control Act (TSCA) states, in part, that any person who exports or intends to export to a foreign country a chemical substance or mixture for which submission of data is required under section 4 or 5(b), or for which a rule, action or order has been proposed or promulgated under section 5, 6, or 7, shall notify the EPA Administrator of such export or intent to export. The Administrator in turn will notify the government of the importing country of EPA's regulatory action with respect to the substance. Legislation is currently pending to address the implementation in the United States of the Rotterdam Convention on Prior Informed Consent (PIC), which itself includes export notification requirements. In order to address these concerns, and additional concerns expressed by other stakeholders, EPA has reported to OMB that as of August 2004, the PIC legislation is not yet in force. EPA

further informed OMB that in 2005, the Agency will reassess the status of the legislation and, if appropriate, will initiate the rulemaking process for considering changes to the TSCA section 12(b) regulation, within the scope of existing statutory authority. This could include holding public meetings and/or issuing an ANPRM that invites interested parties to participate in developing amendments to the current TSCA section 12(b) regulations.

**Statement of Need:**

Industry has nominated the implementing regulations for reform consideration in the annual report on the costs and benefits of regulations, entitled "Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities," that is prepared by the Office of Management and Budget (OMB) and submitted to Congress each year. (See OMB's compilation of comments, summary no. 190, pg 10, commenter no. 12 available at [http://www.whitehouse.gov/omb/infoereg/key\\_comments.html](http://www.whitehouse.gov/omb/infoereg/key_comments.html).)

**Summary of Legal Basis:**

Section 12(b)(2) of the Toxic Substances Control Act (TSCA).

**Alternatives:**

To be determined.

**Anticipated Cost and Benefits:**

Minimal, but yet to be determined.

**Risks:**

None.

**Timetable:**

Action	Date	FR Cite
Notice	08/00/05	

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Additional Information:**

SAN 4858.

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**RIN:** 2070-AJ01

**EPA**

**117. LEAD-BASED PAINT ACTIVITIES;  
VOLUNTARY PROGRAM FOR  
RENOVATION AND REMODELING**

**Priority:**

Other Significant

**Legal Authority:**

15 USC 2682 TSCA 4 402; PL 102-550  
sec 402(c)(3)

**CFR Citation:**

40 CFR 745

**Legal Deadline:**

None

**Abstract:**

As an alternative to the regulatory program, EPA is working with stakeholders to develop a voluntary program for renovations and remodeling activities. The voluntary program would partner the Agency and national organizations together to promote an initiative which could provide incentives to participating contractors and property owners who incorporate lead safe work practices into their standard operating procedures. The Agency plans, in a Notice or ANPRM to be published in the winter of 2004, to introduce the voluntary program, discuss its component parts, and review how it will be evaluated.

**Statement of Need:**

Childhood lead poisoning is a pervasive problem in the United States, with almost a million young children having more than 10 ug/dl of lead in their blood, (Center for Disease

Control's level of concern). Although there have been dramatic declines in blood-lead levels due to reductions of lead in paint, gasoline, and food sources, remaining paint in older houses continues to be a significant source of childhood lead poisoning. These rules will help insure that individuals and firms conducting lead-based paint activities will do so in a way that safeguards the environment and protects the health of building occupants, especially children under 6 years old.

**Summary of Legal Basis:**

TSCA section 402(c) directs EPA to address renovation and remodeling activities by first conducting a study of the extent to which persons engaged in various types of renovation and remodeling activities are exposed to lead in the conduct of such activities or disturb lead and create a lead-based paint hazard on a regular basis. Section 402(c) further directs the Agency to revise the lead-based paint activities regulations (40 CFR part 745 subpart L) to include renovation or remodeling activities that create lead-based paint hazards. In order to determine which contractors are engaged in such activities the Agency is directed to utilize the results of the study and consult with the representatives of labor organizations, lead-based paint activities contractors, persons engaged in remodeling and renovation, experts in health effects, and others.

**Alternatives:**

TSCA section 402(c) states that should the Administrator determine that any category of contractors engaged in renovation or remodeling does not require certification; the Administrator may publish an explanation of the basis for that determination. This voluntary program is one of the key alternatives considered to developing a more prescriptive regulatory program.

**Anticipated Cost and Benefits:**

EPA's quantitative cost estimates fall into four categories: Training Costs, Work Practice Costs, Clearance Testing Costs, and Administrative Costs. The estimates vary depending upon the option selected. In most cases we expect that requirements related to Clearance Testing and Work Practices will contribute the most to overall rule cost. The benefits analysis will not provide direct quantitative measures of each (or any) option. EPA does not have a complete risk assessment (with dose-response functions) that would permit direct quantitative estimates. We

do have other data, such as estimated loadings of Pb generated by renovation work, number and type of renovation events, demographics of the exposed population, and the costs of various health effects previously linked to Pb exposure. With the available information we are able to utilize several qualitative approaches to frame the benefits associated with an effective renovation rule.

**Risks:**

Like the rules under consideration, this voluntary program is aimed at reducing the prevalence and severity of lead poisoning, particularly in children. The Agency has concluded that many R&R work activities can produce or release large quantities of lead and may be associated with elevated blood lead levels. These activities include, but are not limited to: sanding, cutting, window replacement, and demolition. Lead exposure of R&R workers appears to be less of a problem than that of building occupants (especially young children). Some workers (and homeowners) are occasionally exposed to high levels of lead. Any work activity that produces dust and debris may create a lead exposure problem.

**Timetable:**

Action	Date	FR Cite
Notice Announcing 1st Pilot	12/00/04	
Notice Announcing 2nd Pilot	05/00/05	

**Regulatory Flexibility Analysis  
Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Federal, Local, State, Tribal

**Additional Information:**

SAN No. 3557.1; Split from RIN 2070-AC83.



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**RIN:** 2070-AJ03**EPA****PROPOSED RULE STAGE****118. CLEAN AIR FINE PARTICLE  
IMPLEMENTATION RULE****Priority:**

Other Significant

**Unfunded Mandates:**

This action may affect State, local or  
tribal governments and the private  
sector.

**Legal Authority:**

42 USC 7410; 42 USC 7501 et seq

**CFR Citation:**

40 CFR 51

**Legal Deadline:**

None

**Abstract:**

In 1997, EPA promulgated revised  
National Ambient Air Quality  
Standards (NAAQS) for fine particulate  
matter (PM-2.5). The rule described in  
this paragraph—the Implementation  
Rule for PM-2.5 NAAQS—will include  
requirements and guidance for State  
and local air pollution agencies to  
develop and submit State  
implementation plans (SIPs) designed  
to bring the areas into attainment with  
the 1997 standards. These SIP-  
development activities include  
conducting technical analyses to  
identify effective strategies for reducing  
emissions contributing to PM-2.5 levels,  
and adopting regulations as needed in  
order to attain the standards. Ambient

air quality monitoring for 1999-2001  
shows that areas exceeding the  
standards are located throughout the  
eastern half of the United States and  
in California. Estimates show that  
compliance with the standards will  
prevent thousands of premature deaths  
from heart and lung disease, tens of  
thousands of hospital admissions and  
emergency room visits, and millions of  
absences from school and work every  
year.

**Statement of Need:**

This rule is needed in order to provide  
guidance to State and local agencies in  
preparing State Implementation Plans  
(SIPs) designed to bring areas into  
attainment with the 1997 PM-2.5  
standards. The implementation  
requirements for nonattainment areas  
are generally described in subpart 1 of  
section 172 of the Clean Air Act. This  
rule provides further interpretation of  
those requirements for the PM-2.5  
standards.

**Summary of Legal Basis:**

42 USC 7410 and 42 USC 7501 et seq.

**Alternatives:**

Alternatives will be explored as the  
proposal is developed.

**Anticipated Cost and Benefits:**

This information will be provided as  
the proposal is developed.

**Risks:**

The risks addressed by this rule are  
those addressed by the 1997 NAAQS  
rule — i.e., the health and  
environmental risks associated with  
nonattainment of the NAAQS. These  
risks were summarized in detail in the  
analyses accompanying the 1997  
NAAQS rule.

**Timetable:**

Action	Date	FR Cite
NPRM	11/00/04	
Final Action	06/00/05	

**Regulatory Flexibility Analysis  
Required:**

Undetermined

**Government Levels Affected:**

Federal, Local, State, Tribal

**Additional Information:**

SAN No. 4752;

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**RIN:** 2060-AK74**EPA****119. PREVENTION OF SIGNIFICANT  
DETERIORATION (PSD) AND  
NONATTAINMENT NEW SOURCE  
REVIEW (NSR): ALLOWABLES  
PLANTWIDE APPLICABILITY LIMIT  
(PAL), AGGREGATION, AND  
DEBOTTLENECKING****Priority:**

Other Significant

**Legal Authority:**

42 USC 7401 et seq

**CFR Citation:**40 CFR 51.165; 40 CFR 51.166; 40 CFR  
52.21**Legal Deadline:**

None

**Abstract:**

These rules clarify when less than  
significant emissions increases from  
multiple activities at a single major  
stationary source must be considered  
together for the purposes of  
determining major new source review  
(NSR) applicability (aggregation). We  
are also changing in the way emissions  
from permitted emissions units  
upstream or downstream from those  
undergoing a physical change or change  
in the method of operation are  
considered when determining if a  
proposed project will result in a  
significant emissions increase  
(debottlenecking). The rules also  
provide an allowables plantwide  
applicability limit (PAL) option that is  
based on the allowable emissions from  
major stationary sources. A PAL is an  
optional approach that provides the  
owners or operators of major stationary  
sources with the ability to manage

facility-wide emissions without triggering major NSR. The added flexibility of a PAL allows sources to respond rapidly to market changes consistent with the goals of the NSR program. The regulations for aggregation and debottlenecking are intended to improve implementation of the program by articulating principles for determining major NSR applicability that were previously addressed through guidance only. The purpose of the allowables PAL rule is to encourage major stationary sources to install state-of-the-art controls in exchange for regulatory certainty and flexibility.

#### Statement of Need:

The current New Source Review program provides for emissions from multiple projects to be aggregated (aggregation) as one single project under certain circumstances. Similarly, when making a PSD applicability calculation, emissions from units whose effective capacity and potential to emit have been increased as a result of a modification to another unit (debottlenecked units), must be included in the initial PSD applicability calculations. Specific questions regarding the application of these two terms have been addressed on a case-by-case basis. By completing this rulemaking, regulated entities and regulatory agencies will be provided an additional level of certainty in addressing applicability issues. In December 2002 we promulgated NSR rules for a Plantwide Applicability Limit (PAL) based on actual emissions that applies to existing major stationary sources. In 2005, we will propose an allowables PAL based on a facility's allowable emissions mainly for greenfield sources. If a company commits to keep its facility emissions below Allowables PAL level, then these regulations will allow the plant owners to avoid the NSR permitting process when they make changes at individual units at the plant, as long as the total emissions from the facility will not increase. This would provide flexibility for sources to respond rapidly to market changes without compromising environmental protection.

#### Summary of Legal Basis:

42 USC 7411(a)(4)

#### Alternatives:

Alternatives will be developed as the rulemaking proceeds.

#### Anticipated Cost and Benefits:

Cost and benefit information will be developed as appropriate as the rulemaking proceeds.

#### Risks:

Risk information will be developed as appropriate as the rulemaking proceeds.

#### Timetable:

Action	Date	FR Cite
NPRM	02/00/05	
Final Action	10/00/05	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

No

#### Government Levels Affected:

Federal, Local, State, Tribal

#### Additional Information:

SAN No. 4793;

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**RIN:** 2060-AL75

#### EPA

#### 120. PESTICIDES; DATA REQUIREMENTS FOR CONVENTIONAL CHEMICALS

#### Priority:

Other Significant

#### Legal Authority:

7 USC 136(a) to 136(y)

#### CFR Citation:

40 CFR 158

#### Legal Deadline:

None

#### Abstract:

EPA will propose revisions to its data requirements for the registration of

conventional pesticide products. In this action, the Agency will propose revisions to the data requirements that pertain to product chemistry, toxicology, residue chemistry, applicator exposure, post-application exposure, nontarget terrestrial and aquatic organisms, nontarget plant protection, and environmental fate. The proposed data requirements will reflect current scientific knowledge and understanding. These revisions would improve the Agency's ability to make regulatory decisions about the human health and environmental effects of pesticide products to better protect wildlife, the environment, and people, including sensitive subpopulations. Coupled with revision of data requirements, EPA will propose to reformat the requirements and revise its general procedures and policies associated with data submission. By codifying existing data requirements which are currently applied on a case-by-case basis, the pesticide industry, along with other partners in the regulated community, would attain a better understanding and could better prepare for the pesticide registration process. EPA intends to propose a series of revisions to the data requirements, covering different data disciplines and product types.

#### Statement of Need:

Since the data requirements were first published in 1984, the information needed to support the registration of a pesticide has evolved along with the expanding knowledge base of pesticide chemical technology. Over the years, updated data requirements have been applied on a case-by-case basis to support individual registration applications or imposed by data call-in on registrants of similar products. The codified data requirements have not been revised to keep pace with the updated data requirements. EPA will also propose to reformat the data requirements and revise procedures and policies for data submission. The changes to be proposed are intended to provide stakeholders with a more transparent and improved clarity of the potential data requirements, more focused use patterns that reflect current practice, and a more efficient registration process.

#### Summary of Legal Basis:

The planned proposed rule is intended to describe data and information needed to support multiple pesticide mandates under two statutes, specifically the registration, reregistration, registration review,

experimental use permit programs under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the tolerance-setting program under the Federal Food, Drug and Cosmetic Act (FFDCA). FIFRA section 3(c) requires that applicants for registration provide the Agency a full description of tests made and the results that support the registration of a pesticide product, and requires the Agency to issue guidelines specifying the kinds of information needed to support registration. FIFRA section 3(g) requires the Agency to review every 15 years the registration of each pesticide, and determine that it continues to meet the registration standard. The data requirements established for registration will be the foundation of the Agency's registration review. FIFRA section 4 requires the Agency to reregister pesticides that were registered prior to 1984, and in so doing, to provide data and summaries of studies previously submitted to support registration. FIFRA section 5 authorizes the Agency to issue experimental use permits for which data may be required. FFDCA section 408 authorizes EPA to establish tolerances (or exemptions from tolerance) for pesticide residues in food, and prescribes generally the types of data that are to be submitted to support such tolerances.

#### Alternatives:

The Agency is required by its various statutory mandates to establish data requirements that support its regulatory decisions. It is incumbent on the Agency to reevaluate those data requirements in light of scientific advances, analytical improvements, and new technology, in order to provide a sound scientific basis for those decisions. Accordingly, EPA sees no alternative to the overall need to update and revise its data requirements periodically. As it does so, however, each individual data requirement is evaluated against current scientific standards, value and cost, and undergoes an extensive review, including external and public participation, to assess the continued need for the data. The Agency also considers whether alternative regulatory methods, such as restrictions on use, would obviate the need for data, and explores means of introducing flexibility and clarity to reduce burdens on the regulated community.

#### Anticipated Cost and Benefits:

Although estimates may change before the proposal is published, the following estimates are based on the current draft Economic Analysis. Using the currently codified requirements as the baseline for the impact analysis, the total annual impact of the proposed revisions to the pesticide industry is estimated to be about \$50 million. Of this estimated total annual impact, about \$29 million per year represents new data requirements that were imposed over the years but were not specified in the existing CFR. As they have been applied to an increasing number of registrations, these data requirements have become more regularly required and will be proposed for codification. In addition, about \$22 million represents the cost of the proposed modified or expanded existing data requirements for certain tests and use patterns, and about \$2 million represents the cost of proposed new data requirements for data that have not yet been routinely sought. The benefits are difficult to quantify but were an important part of the Agency consideration in developing the proposal. The following parties are expected to benefit: consumers and the general public; farmers and other workers; registrants; animal welfare concerns; scientific, environmental and health communities; State and local governments; EPA and other Federal agencies; and governments outside the United States.

#### Risks:

The revisions to the data requirements to be proposed, like the existing requirements in part 158, would require an applicant for pesticide registration to supply the Agency with information on the pesticide: composition, toxicity, potential human exposure, environmental properties and ecological effects, and efficacy in certain cases. This information is used to assess the human health and environmental risks associated with the product. The data that would be required by this regulation in its current form, and as expected to be proposed, form the foundation of EPA's risk assessment for pesticides, and provide a sound scientific basis for any licensing decisions that impose requirements that mitigate or reduce risks, and that ensure that pesticide residues in food meet the "reasonable certainty of no harm" risk standard of the FFDCA.

#### Timetable:

Action	Date	FR Cite
NPRM	01/00/05	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

Businesses

#### Government Levels Affected:

Federal

#### Additional Information:

SAN 2687.

#### Sectors Affected:

32532 Pesticide and Other Agricultural Chemical Manufacturing

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RIN: 2070-AC12

#### EPA

#### 121. PESTICIDES; EMERGENCY EXEMPTION PROCESS REVISIONS

#### Priority:

Other Significant

#### Legal Authority:

7 USC 136p; 7 USC 136w

#### CFR Citation:

40 CFR 166

#### Legal Deadline:

None

#### Abstract:

EPA will publish a Notice of Proposed Rulemaking in the Federal Register proposing several improvements to the pesticide emergency exemption process under section 18 of the Federal Insecticide, Fungicide, and Rodenticide

Act (FIFRA). Two of these potential improvements are currently being tested through a limited pilot, and are based on recommendations from the States which are the primary applicants for emergency exemptions. EPA has established regulations under section 18 of FIFRA which allow a Federal or State agency to apply for an emergency exemption to allow an unregistered use of a pesticide for a limited time when such use is necessary to alleviate an emergency condition. The proposed revisions would streamline the application and review process, thereby reducing the burden to applicants and EPA, while allowing for quicker emergency response without compromising existing protections for human health and the environment.

#### Statement of Need:

In 1996, stakeholders, including States and Federal agencies, identified a number of issues related to improving the emergency exemption process. States and Federal agencies are the only applicants for emergency exemptions. Representatives of States have recommended modifications to the current process for application, review and approval of emergency exemptions. If adopted, the changes would reduce unnecessary burden to both applicants and EPA, and expedite decisions on applications (which is critical in emergency situations).

#### Summary of Legal Basis:

FIFRA section 18 authorizes EPA to temporarily exempt States from the requirements of registration to alleviate an emergency condition.

#### Alternatives:

EPA has analyzed several measures for streamlining or improving the emergency exemption process, and has received considerable comment, both formally and informally, from stakeholders, including specific recommendations from a group representing States' interests. Since the modifications would generally constitute regulatory relief, and are not expected to cause any adverse economic impact, options with varying cost do not apply.

#### Anticipated Cost and Benefits:

EPA has assessed the potential economic impacts of the proposed improvements and found that they would reduce burdens and costs to States and Federal agencies that apply for emergency exemptions, as well as reduced burden to EPA. The Agency estimates an annual cost reduction of

\$820,000 for applicants and \$120,000 for EPA, for a total of \$940,000. Indirect benefits may accrue to users of pesticides under emergency exemptions if changes result in faster review and approval, or greater availability of pesticides.

#### Risks:

In general, the measures being considered are primarily intended to reduce burdens for States and EPA and achieve efficiencies in the program. No impact on risk is anticipated.

#### Timetable:

Action	Date	FR Cite
Notice: Limited Pilot	04/24/03	68 FR 20145
NPRM	09/03/04	69 FR 53866
NPRM Comment Period End	11/02/04	
Final Action	03/00/06	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

No

#### Government Levels Affected:

Federal, State

#### Additional Information:

SAN No. 4216, EDocket No. OPP-2004-0038;

#### Sectors Affected:

9241 Administration of Environmental Quality Programs

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RIN: 2070-AD36

## EPA

### 122. ACCEPTABILITY OF RESEARCH USING HUMAN SUBJECTS

#### Priority:

Other Significant

#### Legal Authority:

5 USC 301; 7 USC 136a; 7 USC 136w; 15 USC 2603; 21 USC 346a; 42 USC 300v-1(b); 42 USC 7601; 33 USC 1361; 42 USC 9615; 42 USC 11048; 42 USC 6912; 42 USC 300j-9

#### CFR Citation:

40 CFR 26 (Revision)

#### Legal Deadline:

None

#### Abstract:

EPA is evaluating its current policy with respect to the protection of human research subjects in testing. Current EPA regulations in 40 CFR part 26 apply to research conducted or supported by the Agency or "otherwise subject to regulation." No action has been taken yet to give effect to the "otherwise subject to regulation" phrase. In addition, EPA has received the advice of the National Academy of Sciences (NAS) on several issues surrounding the acceptability and interpretation of third party studies involving deliberate dosing of human subjects for the purpose of defining or quantifying toxic endpoints and public comment on an ANPRM. EPA will seek public comment on issues related to Agency use of human research data in its regulatory decisionmaking. EPA believes the process being initiated will serve two important Agency goals: ensuring the availability of sound and appropriate scientific data in its decisions, and protection of the interests, rights and safety of human research subjects. EPA may issue one or more documents, which may include policy statements, rulemaking or requests for public comment.

#### Statement of Need:

In July 1998, the Agency stated that it had not used any human study data for final decisions under the FQPA. The Agency subsequently convened a special joint subcommittee of the FIFRA Scientific Advisory Panel and the EPA Science Advisory Board to advise on this policy. The subcommittee completed its report in September 2000 without reaching consensus on many issues. In December 2001 the Agency sought the advice of the National Academy of Sciences on remaining scientific and ethical issues.

At the same time, the Agency clarified its interim policy, committing, subject to certain exceptions, not to consider or rely on any third party studies involving intentional dosing of human subjects with toxicants for the purpose of defining or quantifying their effects until a final policy is in place, and clarifying that this interim policy applies across all Agency programs. In May 2003 the Agency published an Advance Notice of Proposed Rulemaking on the subject of the acceptability of human studies, posing an array of questions in response to which many comments and suggestions were received. The ANPRM also restated the Agency's intention to issue proposed rules for comment. In June 2003, the U.S. Court of Appeals vacated the December 2001 interim policy on the ground that it constituted an improperly promulgated "rule." The court further stated that as a consequence the Agency's "previous practice of considering third party human studies on a case-by-case basis, applying statutory requirements, the Common Rule, and high ethical standards as a guide," was reinstated "until it is replaced by a lawfully promulgated regulation." In February 2004, the NAS released their report, making many recommendations now under review by the Agency. Some of the Academy's recommendations could only be implemented through rulemaking.

#### Summary of Legal Basis:

Rulemaking concerning human studies is authorized under a variety of provision of the different environmental statutes EPA administers. With respect to pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136), a licensing statute, requires applicants for registration to provide a "full description of tests made and the results thereof" and further authorizes EPA to call in data to maintain a registration under FIFRA sec. 3(c)(2)(B). FIFRA sec. 25(a) provides general rulemaking authority to implement these data requirements, and also to interpret FIFRA sec. 12(a)(2)(P), which makes it unlawful to conduct tests using human subjects unless the subjects volunteer for such tests and are fully informed. Section 408(e) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 348) authorizes the Administrator to issue regulations establishing general procedures and requirements. The Clean Air Act (42 U.S.C. 7601(a)) gives EPA general rulemaking authority. The Clean Water

Act (33 U.S.C. 1361) authorizes the Administrator to promulgate regulations. The Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9615) authorizes the President to establish regulations to implement the statute, this authorizes being delegated to the Administrator under Executive Order 12580. The Emergency Planning and Community Right-to-Know Act (42 U.S.C. 11048) contains a general rulemaking authority. The Resource Conservation and Recovery Act (42 U.S.C. 6912) specifically authorizes the Administrator to prescribe regulations to carry out the functions under the Act. The Safe Drinking Water Act (42 U.S.C. 300j-9) authorizes the Administrator to prescribe regulations that are necessary and appropriate to carry out EPA's functions under the Act. In addition, EPA has broad authority under 5 U.S.C. 301 and 42 U.S.C. 300v-1(b).

#### Alternatives:

Still to be identified.

#### Anticipated Cost and Benefits:

No analysis has been performed yet.

#### Risks:

No analysis has been performed yet.

#### Timetable:

Action	Date	FR Cite
ANPRM	05/07/03	68 FR 24410
Notice	01/00/05	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

No

#### Government Levels Affected:

Federal

#### Additional Information:

SAN No. 4610, EDocket No. OPP-2003-0132;

#### Sectors Affected:

32532 Pesticide and Other Agricultural Chemical Manufacturing

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RIN: 2070-AD57

#### EPA

#### 123. INCREASE METALS RECLAMATION FROM F006 WASTE STREAMS

#### Priority:

Other Significant

#### Unfunded Mandates:

Undetermined

#### Legal Authority:

Not Yet Determined

#### CFR Citation:

40 CFR 261

#### Legal Deadline:

None

#### Abstract:

Many metal finishers and other industrial sectors generate an electroplating sludge as part of their production process that is amenable to recycling, i.e., the sludge contains economically recoverable amounts of metals such as copper, nickel, zinc, etc. Currently, these sludges (F006) are listed hazardous wastes subject to RCRA regulations. Many generators continue to send these sludges for treatment and disposal when they could be recycled. Similarly, generators currently sending their sludges for recycling receive no economic benefit for this practice. Since the mid-1990s, EPA has been working with industry and the States to create incentives for safe recycling and has promulgated rules to foster this practice. However, EPA is interested in exploring whether further regulatory changes are warranted.

EPA is currently evaluating several options that would provide regulatory relief to generators and handlers of F006. All options would reduce regulatory costs to generators and handlers relative to the current RCRA subtitle C regulatory program.

#### Statement of Need:

F006 represents one of the largest hazardous waste streams amenable to recycling. Currently, there is no differentiation in regulatory requirements between the land disposal and recycling of F006 electroplating sludges. This effort seeks to evaluate different regulatory options that would eliminate existing disincentives to the safe recycling of F006 with the ultimate objective of possibly proposing changes to the existing regulatory framework. Potential benefits to be achieved include increasing the economic competitiveness of small businesses, increasing the waste minimization and recycling of F006, and increasing natural resource conservation by reducing emissions from landfills and surface waters.

#### Summary of Legal Basis:

RCRA sections 2002, 3001-3004, 42 U.S.C. 6912, 6921-6924. No aspect of this action is required by statute or court order.

#### Alternatives:

Regulatory options being examined would affect generators and possibly other handlers of F006, i.e., consolidators, commercial hazardous waste recyclers and mineral processing facilities. EPA is also considering various options for the minimum amount of recoverable metals contained in F006 electroplating sludges.

#### Anticipated Cost and Benefits:

This rule is designed to provide regulatory relief to generators and possibly other handlers of F006. Potential benefits to be achieved include increasing the economic competitiveness of small businesses, increasing the waste minimization and recycling of F006 and increasing natural resource conservation by reducing emissions from landfills and surface waters.

#### Risks:

Options being evaluated would ensure that the risks posed from recycling F006 would not increase. These include risks from storage and management of the materials throughout the recycling process, as well risks from any non-recyclable constituents included in the F006.

#### Timetable:

Action	Date	FR Cite
NPRM	09/00/05	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

No

#### Government Levels Affected:

Undetermined

#### Federalism:

Undetermined

#### Additional Information:

SAN No. 4651

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RIN: 2050-AE97

#### EPA

#### 124. REGULATORY AMENDMENTS TO THE F019 HAZARDOUS WASTE LISTING TO EXCLUDE WASTEWATER TREATMENT SLUDGES FROM CHEMICAL CONVERSION COATING PROCESS (ZINC PHOSPHATING) OF AUTOMOBILE BODIES OF ALUMINUM

#### Priority:

Other Significant

#### Unfunded Mandates:

Undetermined

#### Legal Authority:

42 USC 1006 et seq

#### CFR Citation:

40 CFR 261.31; 40 CFR 302.4

#### Legal Deadline:

None

#### Abstract:

Automobile manufacturers are adding aluminum or aluminized components

to automobiles to reduce the weight of vehicles to increase fuel economy. When aluminum components are added to the automobile assembly process, the current Federal regulations require that the wastewater treatment sludges generated from this conversion coating process be managed as a hazardous waste under the Resource Conservation and Recovery Act. EPA intends to reduce burden on the regulated community by revising the current RCRA regulations that apply to the wastewater treatment sludges from the chemical conversion coating (zinc phosphating) of aluminum.

#### Statement of Need:

This action when finalized will reduce the burden on the automobile industry from treating sludges from the process of zinc phosphating of aluminum as hazardous wastes. The applicable listed hazardous waste (F019) was listed as such because it contains cyanide and chromium. The sludges from the zinc phosphating of aluminum do not contain any of these constituents.

#### Timetable:

Action	Date	FR Cite
NPRM	11/00/05	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

No

#### Government Levels Affected:

Undetermined

#### Additional Information:

SAN No. 4834;

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RIN: 2050-AG15

**EPA****125. TOXICS RELEASE INVENTORY REPORTING BURDEN REDUCTION RULE****Priority:**

Other Significant

**Legal Authority:**

42 USC 11023 et seq

**CFR Citation:**

40 CFR 372

**Legal Deadline:**

None

**Abstract:**

The primary goal of this effort by EPA is to reduce burdens associated with Toxics Release Inventory (TRI) reporting while at the same time continuing to provide valuable information to the public consistent with the goals and statutory requirements of the TRI program.

**Statement of Need:**

EPA is looking to explore various options with the intention of identifying a specific burden reduction initiative that effectively lessens the burden on facilities but at the same time ensures that TRI continues to provide communities with the same high level of significant chemical release and other waste management information.

**Summary of Legal Basis:**

Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 and section 6607 of the Pollution Prevention Act (PPA) of 1990.

**Alternatives:**

Still under analysis.

**Anticipated Cost and Benefits:**

Still under analysis.

**Risks:**

Not applicable.

**Timetable:**

Action	Date	FR Cite
NPRM	01/00/05	
Final Action	02/00/07	

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

Federal, State

**Additional Information:**

SAN No. 4896;

**URL For More Information:**

www.epa.gov/tri

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**RIN:** 2025-AA14**EPA****FINAL RULE STAGE****126. CLEAN AIR VISIBILITY RULE****Priority:**

Economically Significant

**Legal Authority:**

42 USC 7410; 42 USC 7414; 42 USC 7421; 42 USC 7470 to 7479; 42 USC 7491; 42 USC 7492; 42 USC 7601; 42 USC 7602

**CFR Citation:**

40 CFR 51.308(e)(1); 40 CFR 51 app Y (New)

**Legal Deadline:**

NPRM, Judicial, April 15, 2004,  
Consent Decree: April 15, 2004.

Final, Judicial, April 15, 2005, Consent Decree: April 15, 2005.

**Abstract:**

To meet the Clean Air Act's requirements, EPA published the regional haze rule on July 1, 1999 (64 FR 35714). On May 24, 2002, the DC Circuit vacated certain provisions of the regional haze rule related to best available retrofit technology (BART). Because of this court decision, we need to propose and publish revised BART provisions in the regional haze rule. The purpose of this effort is to provide the appropriate changes to the BART

requirements and guidelines, and to address additional issues related to reasonable progress goals for the visibility program. On July 20, 2001, we proposed guidelines intended to add further clarifications to the BART requirements in the regional haze rule. Since then, due to additional information that has come to light since that proposal, we have decided that a supplemental proposal is needed. The supplemental proposal was published on May 5, 2004.

**Statement of Need:**

This action is needed in response to the May 2002 ruling of the U.S. Court of Appeals for the D.C. Circuit (American Corn Growers et al. V. EPA., 291 F.3d 1) vacating the Best Available Retrofit Technology (BART) provisions of the regional haze rule. The Clean Air Act requires that States to include BART in their visibility State Implementation Plans (SIPs). The Clean Air Act also requires that a State take steps to prevent emissions from sources located within its boundaries from interfering with a downwind State's ability to meet air quality standards, or interfering with measures to protect visibility.

**Summary of Legal Basis:**

Clean Air Act section 169A requires States to include BART in their visibility SIPs. Clean Air Act section 110(a)(2)(D) (42 USC 7410(a)(2)(D)) requires that each state's implementation plan include the "good neighbor" provisions of prohibiting sources in the State from emitting air pollutants in amounts that contribute significantly to nonattainment in a downwind state, or interfere with measures to protect visibility in a Class I areas. Section 110(a)(1) (42 USC 7410(a)(1)) requires States to submit implementation plans within a specified period of time after the promulgation of a new or revised national ambient air quality standard. In addition, EPA has authority under section 110(k)(5) (42 USC 7410(k)(5)) to require States to revise existing implementation plans whenever EPA finds that those plans are inadequate to comply with any requirement. Further, section 301(a)(1) (42 USC 7601(a)(1)) confers general authority upon the EPA Administrator. These provisions of the Clean Air Act confer authority on EPA to promulgate the present regulations.

**Alternatives:**

This entry comprises the action the Agency plans to take to implement the

BART provisions of the Clean Air Act. The major alternatives facing the Agency include: (1) How to structure the process for exempting individual emission sources from BART that is mandated by the court ruling, and (2) whether to include prescriptive control levels for visibility-impairing pollution from large electric generating units, and what control levels to prescribe.

#### Anticipated Cost and Benefits:

EPA prepared a regulatory impact analysis (RIA) for the proposed BART rule. Updated cost and benefit calculations will be made as development of the RIA proceeds for the final rulemaking.

#### Risks:

The risks addressed are the health and welfare impacts resulting from emissions that interfere with measures to protect visibility in Class I areas. These effects were outlined in detail in the Regulatory Impact Analysis for the proposed BART rulemaking.

#### Timetable:

Action	Date	FR Cite
NPRM	07/20/01	66 FR 38108
Supplemental NPRM	05/05/04	69 FR 25184
Final Action	04/00/05	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

No

#### Government Levels Affected:

Federal, Local, State, Tribal

#### Federalism:

Undetermined

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SAN No. 4450;

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RIN: 2060-AJ31

#### EPA

### 127. CLEAN AIR MERCURY RULE—ELECTRIC UTILITY STEAM GENERATING UNITS

#### Priority:

Economically Significant. Major under 5 USC 801.

#### Unfunded Mandates:

This action may affect State, local or tribal governments and the private sector.

#### Legal Authority:

42 USC 7412; 42 USC 7411

#### CFR Citation:

40 CFR 63; 40 CFR 60

#### Legal Deadline:

NPRM, Judicial, December 15, 2003.

Final, Judicial, March 15, 2005.

#### Abstract:

On January 30, 2004, the EPA proposed alternative approaches to regulating mercury emissions from coal-fired electric utility steam generating units and nickel emissions from oil-fired electric utility steam generating units.

#### Statement of Need:

Oil and coal-fired electric utility steam generating units were added (December 20, 2000) to the list of source categories to be regulated under section 112 of the Clean Air Act, as amended. On January 30, 2004, EPA proposed to remove oil- and coal-fired electric utility steam generating units from the list so that they could be regulated under section 111 of the Clean Air Act.

#### Summary of Legal Basis:

Sections 111 and 112 of the Clean Air Act, as amended.

#### Alternatives:

Alternative approaches to regulating electric utility steam generating units were proposed on January 30, 2004.

#### Anticipated Cost and Benefits:

It is anticipated that this rule will result in significant costs to the affected industry, including Federal, State, and local entities that own/operate electric utility steam generating units. These costs will be identified as the final rule is developed.

#### Risks:

Risk information will become available as the final rule is developed.

#### Timetable:

Action	Date	FR Cite
NPRM	01/30/04	69 FR 4754
Supplemental NPRM	03/16/04	69 FR 12298
Notice of Reopening Comment Period	05/05/04	69 FR 25052
NODA	11/00/04	
Final Action	03/15/05	

#### Regulatory Flexibility Analysis Required:

Undetermined

#### Small Entities Affected:

Businesses

#### Government Levels Affected:

Federal, Local, State, Tribal

#### Additional Information:

SAN No. 4571, EDocket No. OAR-2002-0056;

#### Sectors Affected:

221112 Fossil Fuel Electric Power Generation

#### URL For More Information:

[www.epa.gov/ttn/atw/utility/utltoxp.html](http://www.epa.gov/ttn/atw/utility/utltoxp.html)

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RIN: 2060-AJ65

#### EPA

### 128. CLEAN AIR OZONE IMPLEMENTATION RULE (PART 1 AND PART 2)

#### Priority:

Economically Significant. Major under 5 USC 801.

#### Unfunded Mandates:

This action may affect the private sector under PL 104-4.

#### Legal Authority:

42 USC 7408; 42 USC 7410; 42 USC 7501 to 7511f; 42 USC 7601(a)(1)



**CFR Citation:**

40 CFR 51; 40 CFR 50; 40 CFR 81

**Legal Deadline:**

None

**Abstract:**

This rule would provide specific requirements for State and local air pollution control agencies and Tribes to prepare State Implementation Plans (SIPs) and Tribal Implementation Plans (TIPs) under the 8-hour national ambient air quality standard (NAAQS) for ozone, published by EPA on July 18, 1997. The Clean Air Act (CAA) requires EPA to set ambient air quality standards and requires States to submit SIPs to implement those standards. The 1997 standards were challenged in court, but in February 2001, the Supreme Court determined that EPA has authority to implement a revised ozone standard, but ruled that EPA must reconsider its implementation plan for moving from the 1-hour standard to the revised standard. The Supreme Court identified conflicts between different parts of the CAA related to implementation of a revised NAAQS, provided some direction to EPA for resolving the conflicts, and left it to EPA to develop a reasonable approach for implementation. Thus, this rulemaking must address the requirements of the CAA and the Supreme Court's ruling. This rule would provide detailed provisions to address the CAA requirements for SIPs and TIPs and would thus affect States and tribes. States with areas that are not attaining the 8-hour ozone NAAQS will have to develop—as part of their SIPs—emission limits and other requirements to attain the NAAQS within the timeframes set forth in the CAA. Tribal lands that are not attaining the 8-hour ozone standard may be affected, and could voluntarily submit a TIP, but would not be required to submit a TIP. In cases where a TIP is not submitted, EPA would have the responsibility for planning in those areas.

**Statement of Need:**

This action is needed in response to the U.S. Supreme Court's ruling in February 2001 (*Whitman v. American Trucking Assoc.*, 121 S.Ct.903) that stated that EPA has the authority to implement a revised ozone NAAQS but that EPA could not ignore the provisions of subpart 2 when implementing the 8-hour NAAQS. The Supreme Court identified several portions of subpart 2 that are ill-fitted to the revised NAAQS but left it to EPA

to develop a reasonable implementation approach. Consequently, EPA is developing a rule to implement the 8-hour ozone NAAQS under the provisions of subpart 2 of the CAA.

**Summary of Legal Basis:**

Title I of the Clean Air Act

**Alternatives:**

This entry comprises the action the Agency plans to take to implement the 8-hour ozone NAAQS. The major alternatives facing the Agency is whether the 8-hour O<sub>3</sub> NAAQS should be implemented under the less prescriptive part of the Clean Air Act (title I, part D, subpart 1) or the more prescriptive part of the Act (subpart 2). Another major set of alternatives concern the kind of transition EPA should make from implementation of the current 1-hour ozone standard to the new 8-hr ozone standard.

**Anticipated Cost and Benefits:**

EPA prepared a regulatory impact analysis for the final ozone NAAQS, and has prepared a cost analysis for the proposed implementation rule. The benefits of the rule are those associated with attainment of the ozone NAAQS including significant improvements in premature mortality, chronic asthma, chronic and acute bronchitis, upper and lower respiratory symptoms, work days lost, decreased worker productivity, visibility in urban and suburban areas, and increases in yields of commercial forests currently exposed to elevated ozone levels.

**Risks:**

The risks addressed by this action are the likelihood of experiencing increased health and environmental effects associated with nonattainment of the National Ambient Air Quality Standard for ozone. These effects are briefly described above in the "costs and benefits" section, and they were outlined in detail in the Regulatory Impact Analysis for the ozone NAAQS rulemaking. The results are summarized in the Federal Register notice for that rulemaking (62 FR 38856, July 18, 1997).

**Timetable:**

Action	Date	FR Cite
NPRM	06/02/03	68 FR 32802
Final Action (Phase 1)	04/30/04	69 FR 23951
Final Action (Phase 2)	11/00/04	

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

Local, State, Tribal

**Additional Information:**

SAN No. 4625;

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**RIN:** 2060-AJ99**EPA****129. • NONATTAINMENT MAJOR NEW SOURCE REVIEW (NSR)****Priority:**

Other Significant

**Legal Authority:**

42 USC 7401 et seq

**CFR Citation:**

40 CFR 51, app S

**Legal Deadline:**

None

**Abstract:**

This final action will promulgate changes to regulations that govern NSR permitting of major stationary sources in nonattainment areas where there is no approved SIP. Appendix S of 40 CFR part 51 contains the permitting program for major stationary sources in nonattainment areas in transition periods before approval of a SIP to implement part D of title I. This final action will revise appendix S to conform it to the changes made to regulations at 40 CFR 51.165 for SIP programs for nonattainment major NSR. (67 FR 80816; December 31, 2002)

**Statement of Need:**

In August 1992, EPA voluntarily initiated a comprehensive effort to reform the NSR process. This effort was

initiated to examine complaints from the regulated community that the current regulatory scheme is too complex, needlessly delays projects, and unduly restricts source flexibility. Currently there are no applicable statutory or judicial deadlines for the NSR reform rulemaking effort. The goal of this effort is to address industry's concerns without sacrificing the environmental benefits embodied in the present approach; that is, protecting and improving local air quality, and stimulating pollution prevention and advances in control technologies. In July 1993, the NSR Reform Subcommittee of the CAA Advisory Committee was formed. The Subcommittee's purpose is to provide independent advice and counsel to EPA on policy and technical issues associated with reforming the NSR rules. The Subcommittee was composed of representatives from industry, State/local air pollution control agencies, environmental organizations, EPA headquarters and regions, and other Federal agencies (National Park Service and Forest Service, Department of Energy, and the Office of Management and Budget).

**Summary of Legal Basis:**

Clean Air Act sections 165 and 173.

**Alternatives:**

The Subcommittee discussed numerous options for implementing NSR reform. However, EPA's primary focus has been to consider the specific recommendations developed by the Subcommittee and, where appropriate, use them in this rulemaking effort. In January 1996, EPA, as part of another regulatory streamlining measure, merged portions of a separate rulemaking to implement the 1990 CAA Amendments with the Reform effort. The combined package was proposed in the Federal Register on July 23, 1996. On July 24, 1998, EPA issued another Federal Register Notice seeking comment on two applicability provisions. On February 2-3, 1999, EPA convened a public meeting to listen to new stakeholder proposals for streamlining NSR applicability and control technology requirements. Stakeholder groups submitted written proposals during May and June 1999.

**Anticipated Cost and Benefits:**

From a cost perspective, the proposed rulemaking represents a decrease in applications and recordkeeping costs to industry of at least \$13 million per year, as compared to the preexisting program, based primarily on the fact

that fewer sources will need to apply for major source permits. In addition, the cost to State and local agencies will be reduced by approximately \$1.4 million per year. The Federal Government should realize a savings of approximately \$116,000 per year. Additional cost reductions, which are difficult to quantify, will be realized due to the streamlining effect of the rulemaking on the permitting process, for example, the opportunity costs for shorter time periods between permit application and project completion and reduced uncertainty in planning for future source growth.

**Risks:**

This is a procedural rule applicable to a wide variety of source categories. Moreover, it applies to criteria pollutants for which NAAQS have been established. This action is considered environmentally neutral. However, any potential risks are considered in the NAAQS rulemaking from a national perspective.

**Timetable:**

Action	Date	FR Cite
Final Action	11/00/04	

**Regulatory Flexibility Analysis Required:**

Undetermined

**Government Levels Affected:**

Federal, Local, State

**Additional Information:**

SAN No. 3259.2; Split from RIN 2060-AE11. See also SAN 4390

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**RIN:** 2060-AM59

**EPA****130. TEST RULE; TESTING OF CERTAIN HIGH PRODUCTION VOLUME (HPV) CHEMICALS****Priority:**

Other Significant

**Legal Authority:**

15 USC 2603; 15 USC 2611 to 2612; 15 USC 2625 to 2626

**CFR Citation:**

40 CFR 790 to 799

**Legal Deadline:**

None

**Abstract:**

EPA is proposing test rules under section 4(a) of the Toxic Substances Control Act (TSCA) to require testing and recordkeeping requirements for certain high production volume (HPV) chemicals (i.e., chemicals which are manufactured (including imported) in the aggregate at more than 1 million pounds on an annual basis) that have not been sponsored under the voluntary HPV Challenge Program. Although varied based on specific data needs for the particular chemical, the data generally collected under these rules may include: Acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate. The first rule proposed testing for 37 HPV chemicals with substantial worker exposure. The number of chemicals included in the first final rule may be reduced based on new information on annual production volumes, worker exposure, and commitments to the voluntary HPV Challenge Program. Subsequent test rules will require similar screening level testing for other unsponsored HPV Challenge Program chemicals.

**Statement of Need:**

EPA has found that, of those non-polymeric organic substances produced or imported in amounts equal to or greater than 1 million pounds per year based on 1990 reporting for EPA's Inventory Update Rule (IUR), only 7 percent have a full set of publicly available internationally recognized basic health and environmental fate/effects screening test data. Of the over 2,800 HPV chemicals based on 1990 data, 43 percent have no publicly available basic hazard data. For the remaining chemicals, limited amounts of the data are available. This lack of available hazard data compromises EPA's and others' ability to determine

whether these HPV chemicals pose potential risks to human health or the environment, as well as the public's right to know about the hazards of chemicals that are found in their environment, their homes, their workplaces, and the products that they buy. It is EPA's intent to close this knowledge gap. EPA believes that for most of the HPV chemicals, insufficient data are readily available to reasonably determine or predict the effects on health or the environment from the manufacture (including importation), distribution in commerce, processing, use, or disposal of the chemicals, or any combination of these activities. EPA has concluded that a program to collect and, where needed, develop basic screening level toxicity data is necessary and appropriate to provide information in order to assess the potential hazards/risks that may be posed by exposure to HPV chemicals. On April 21, 1998, a national initiative, known as the Chemical Right-To-Know Initiative, was announced in order to empower citizens with knowledge about the most widespread chemicals in commerce—chemicals that people may be exposed to in the places where they live, work, study, and play. A primary component of EPA's Chemical Right-To-Know (ChemRTK) initiative is the voluntary HPV Challenge Program, which was created in cooperation with industry, environmental groups, and other interested parties, and is designed to assemble basic screening level test data on the potential hazards of HPV chemicals while avoiding unnecessary or duplicative testing. Data needs which remain unmet in the voluntary HPV Challenge Program may be addressed through the international efforts or rulemaking.

#### Summary of Legal Basis:

These test rules will be issued under section 4(a)(1)(B) of TSCA. Section 2(b)(1) of TSCA states that it is the policy of the United States that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture (which is defined by statute to include import) and those who process such chemical substances and mixtures(.)" To implement this policy, TSCA section 4(a) mandates that EPA require by rule that manufacturers and processors of chemical substances and mixtures conduct testing if the Administrator finds that: (1)(A)(i) the manufacture,

distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment, (ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or (B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture, (ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

#### Alternatives:

The strategy and overall approach that EPA is using to address data collection needs for U.S. HPV chemicals includes a voluntary component (the HPV Challenge Program), certain international efforts, and these rulemakings under TSCA. The issuance of a rulemaking is often the Agency's final mechanism for obtaining this important information.

#### Anticipated Cost and Benefits:

The potential benefits of these test rules are substantial, as no one—whether in industry, government, or the public—can make reasoned risk management decisions in the absence of reliable health and environmental information. The cost of the baseline screening testing that would be imposed is estimated to be about \$200,000 per chemical for a full set of tests. It is unlikely, however, for a chemical to need a full set of tests, which would only occur if none of the data in question already exists.

#### Risks:

Data collected and/or developed under these test rules, when combined with information about exposure and uses,

will allow the Agency and others to evaluate and prioritize potential health and environmental effects and take appropriate follow up action.

#### Timetable:

Action	Date	FR Cite
NPRM	12/26/00	65 FR 81658
Final Action	12/00/04	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

Businesses

#### Government Levels Affected:

Federal

#### Additional Information:

SAN 3990. See also the Regulatory Plan entry entitled Chemical Right-to-Know Initiative (RIN 2070-AD25; SAN 4176).

#### Sectors Affected:

325 Chemical Manufacturing; 32411 Petroleum Refineries

#### URL For More Information:

[www.epa.gov/opptintr/chemtest/sect4rule.htm](http://www.epa.gov/opptintr/chemtest/sect4rule.htm)

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RIN: 2070-AD16

#### EPA

**131. NESHAPS: STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR HAZARDOUS WASTE COMBUSTORS (PHASE I FINAL REPLACEMENT STANDARDS AND PHASE II)**

#### Priority:

Other Significant

**Legal Authority:**

42 USC 6924 RCRA 3004; 42 USC 6925 RCRA 3005; 42 USC 7412 CAA 112; 42 USC 7414 CAA 114

**CFR Citation:**

40 CFR 63; 40 CFR 264; 40 CFR 265; 40 CFR 266; 40 CFR 270

**Legal Deadline:**

NPRM, Judicial, March 31, 2004, Consent decree for Phase 2 portion of rule.

Final, Judicial, June 14, 2005, Consent decree.

**Abstract:**

On September 30, 1999, EPA promulgated standards to control emissions of hazardous air pollutants from incinerators, cement kilns, and lightweight aggregate kilns that burn hazardous waste (referred to as the Phase I Rule). A number of parties, representing interests of both industry and the environmental community, sought judicial review of the rule. The Court ruled against EPA and vacated the Phase I rule. On October 19, 2001, EPA, together with all petitioners, filed a joint motion asking the Court to stay the issuance of its mandate to allow them time to develop interim standards. These stop-gap interim standards were promulgated on February 13 and 14, 2002. They replace the vacated standards temporarily, until revised replacement standards are promulgated by June 14, 2005. EPA will ultimately finalize the Phase I replacement standards. Also, EPA is developing emission standards for hazardous waste burning industrial, institutional, commercial boilers, process heaters, and hydrochloric acid production furnaces. These sources are referred to as Phase II Sources because the standards were originally scheduled to be promulgated after Phase I source standards were finalized; however, a separate consent decree now requires us to finish developing emission standards for the Phase II sources by the same date as those for Phase I (June 14, 2005). EPA has developed options for calculating the emission standards that are considered to be consistent with both the statutory requirements and the opinion of the Court. EPA has proposed emission standards and compliance provisions for both the Phase I and Phase II sources.

**Statement of Need:**

Section 112 of the Clean Air Act requires that the EPA promulgate the regulations requiring the control of

hazardous air pollutants from major and certain area sources. The control of hazardous air pollutants is achieved through promulgation of emission standards under sections 112(d) and (f) and, in appropriate circumstances, work practice standards under section 112(h).

On September 30, 1999 EPA promulgated standards to control emissions of hazardous air pollutants from incinerators, cement kilns, and lightweight aggregate kilns that burn hazardous waste (referred to as the Phase I Rule). A number of parties, representing interests of both industry and the environmental community, sought judicial review of the rule. The Court ruled against EPA and vacated the Phase I rule.

**Summary of Legal Basis:**

On October 19, 2001, EPA, together with all petitioners, filed a joint motion asking the Court to stay the issuance of its mandate to allow time to develop interim standards. These stop-gap interim standards were promulgated on February 13 and 14, 2002. They replace the vacated standards temporarily, until revised replacement standards are promulgated by June 14, 2005. EPA is working towards promulgation by this date. EPA is also developing emission standards for hazardous waste burning industrial, institutional, commercial boilers, process heaters, and hydrochloric acid production furnaces. These sources are referred to as Phase II Sources because the standards were originally scheduled to be promulgated after Phase I source standards were finalized; however, a separate consent decree now requires us to finish developing emission standards for the Phase II sources by the same date as those for Phase I (June 14, 2005).

**Alternatives:**

EPA has developed several options for calculating the emission standards and has included these options in the April 20, 2004 proposal.

**Anticipated Cost and Benefits:**

Estimated costs and benefits for the proposed standards are summarized in the April 20, 2004 proposal.

**Risks:**

For the 1999 rule, we estimated the avoided incidence of mortality and morbidity associated with reductions in particulate matter (PM) emissions. Estimates of cases of mortality and morbidity avoided were made for children and the elderly, as well as the general population, using

concentration-response functions derived from human epidemiological studies. Morbidity effects included respiratory and cardiovascular illnesses requiring hospitalization, as well as other illnesses not requiring hospitalization, such as acute and chronic bronchitis and acute upper and lower respiratory symptoms. For this rule, we are comparing characteristics of the sources covered by the 1999 rule to the sources covered by the replacement rule that are related to risk. These characteristics include emissions, stack characteristics, meteorology, and population. Based on the results of the statistical comparisons, we will infer whether the risks will be about the same, less than, or greater than the 1999 rule. Risk inferences for boilers and HCl production furnaces will be based on comparisons with incinerators for the 1999 rule. The risk estimates for the proposed standards are summarized in the April 20, 2004 proposal.

**Timetable:**

Action	Date	FR Cite
NPRM-CK	04/19/96	61 FR 17358
Final-Fasttrack	06/19/98	63 FR 33782
Final-CK	09/30/99	64 FR 52828
NODA	07/27/00	65 FR 39581
DF 1	07/03/01	66 FR 35087
NPRM-Phase1	07/03/01	66 FR 35126
Parallel Proposal	07/03/01	66 FR 35124
Direct Final Action	10/15/01	66 FR 52361
Final Compliance Exten.	12/06/01	66 FR 63313
Interim Final Action	02/13/02	67 FR 6792
Final HAP	02/14/02	67 FR 6968
NPRM-Phases 1&2	04/20/04	69 FR 21197
Final Action	06/00/05	

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Federal, State, Tribal

**Additional Information:**

SAN No. 3333, EDocket No. OAR-2004-0022; For information on the Phase I portion of this effort, see SAN 4418, RIN 2050-AE79.

**Sectors Affected:**

3335 -; 3343 Audio and Video Equipment Manufacturing; 3251 Basic Chemical Manufacturing; 3273 Cement and Concrete Product Manufacturing; 3271 Clay Product and Refractory Manufacturing; 3328 Coating, Engraving, Heat Treating and Allied

Activities; 3342 Communications Equipment Manufacturing; 3341 Computer and Peripheral Equipment Manufacturing; 2211 Electric Power Generation, Transmission and Distribution; 45431 Fuel Dealers; 3332 Industrial Machinery Manufacturing; 3274 Lime, Gypsum and Gypsum Product Manufacturing; 3327 Machine Shops, Turned Product, and Screw, Nut and Bolt Manufacturing; 3362 Motor Vehicle Body and Trailer Manufacturing; 3361 Motor Vehicle Manufacturing; 3363 Motor Vehicle Parts Manufacturing; 2123 Non-Metallic Mineral Mining and Quarrying; 3259 Other Chemical Product Manufacturing; 3329 Other Fabricated Metal Product Manufacturing; 3339 Other General Purpose Machinery Manufacturing; 3279 Other Nonmetallic Mineral Product Manufacturing; 3255 Paint, Coating, Adhesive, and Sealant Manufacturing; 3253 Pesticide, Fertilizer and Other Agricultural Chemical Manufacturing; 3241 Petroleum and Coal Products Manufacturing; 4227 Petroleum and Petroleum Products Wholesalers; 3254 Pharmaceutical and Medicine Manufacturing; 3231 Printing and Related Support Activities; 5629 Remediation and Other Waste Management Services; 3252 Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing; 3344 Semiconductor and Other Electronic Component Manufacturing; 22132 Sewage Treatment Facilities; 5622 Waste Treatment and Disposal

**URL For More Information:**

[www.epa.gov/hwcmact/](http://www.epa.gov/hwcmact/)

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**RIN:** 2050-AE01

**EPA****132. HAZARDOUS WASTE MANIFEST REGULATION****Priority:**

Other Significant

**Legal Authority:**

42 USC 6922 RCRA 3002; 42 USC 6923 RCRA 3003; 42 USC 6924 RCRA 3004; 42 USC 6926 RCRA 3006; PL 105-277; Government Paperwork Elimination Act 17

**CFR Citation:**

40 CFR 260; 40 CFR 262; 40 CFR 263; 40 CFR 264; 40 CFR 265; 40 CFR 271

**Legal Deadline:**

None

**Abstract:**

The Uniform Hazardous Waste Manifest (Form 8700-22) is a multi-copy form used to identify the quantity, composition, origin, routing, and destination of hazardous waste during its transportation. Waste handlers (e.g., generators and transporters) are required to use the manifest, and States may not require a different manifest in its place. However, the manifest has State blocks which allow States, at their option, to require the entry of additional specific information to serve their State's regulatory needs. Under the current regulations more than 20 states print the manifest form in accordance with the format specified in Federal regulations. However, the variability among State manifest programs associated with State optional blocks, different copy distribution schemes, and the manifest hierarchical acquisition scheme has drawn complaints from the regulated community. Variability among States' manifest programs and the manifest system's current reliance on paper result in significant paperwork and cost burden to waste handlers and States who choose to collect manifest information. The Agency intends to standardize further the manifest form elements, and to specify one format for the manifests that may be used in all States. In addition, the Agency intends to announce standard requirements for tracking rejected wastes, container residues, and international shipments of hazardous wastes. Finally, the Agency intends to pursue an optional approach that would use information technologies to conduct the manifest process electronically, thereby reducing paperwork burden, and improving the speed and accuracy of preparing, transmitting, and recordkeeping the

manifest form. However, the Agency will bifurcate the manifest rule so that the form revisions may be expedited, while additional analysis on the e-manifest continues.

**Statement of Need:**

Since the adoption of the Uniform Manifest by EPA and the Department of Transportation (DOT) in 1984, the regulated community and authorized States have pressed EPA to adopt changes that would simplify and further reduce the variability among the hazardous waste manifest forms required and distributed by the States. In addition, the recent focus on electronic government has highlighted the potential advantages of an electronic manifest system in terms of reduced paperwork burdens and more timely waste tracking. This action responds to these needs with a truly universal set of manifest data elements and a manifest format that will be identical in all States, as well as standards that will allow the manifest data to be completed, signed, transmitted, and recorded electronically.

**Summary of Legal Basis:**

EPA's regulations implementing the manifest are based on section 3002(a)(5) of the RCRA statute, which requires that EPA include in its hazardous waste generator regulations requirements addressing the "use of a manifest system and any other reasonable means necessary" to assure that all such hazardous waste is designated for and arrives at treatment, storage, or disposal facilities that have been permitted under RCRA subtitle C requirements. Section 3003(a)(3) of the Act requires transporters of hazardous waste to comply with the manifest system, while section 3004(a)(2) requires compliance with the manifest system by treatment, storage, and disposal facilities. Moreover, according to section 1004(12) of the Act, the manifest is defined as the "form used for identifying the quantity, composition, and the origin, routing, and destination of hazardous waste during its transportation from the point of generation to the point of disposal, treatment, or storage." The manifest also serves as the "shipping paper" meeting DOT requirements for the transportation of hazardous materials under the Federal Hazardous Materials laws and regulations.

EPA's current manifest regulations require generators to obtain manifest forms from the authorized States. The generator must complete the paper form by identifying the type and quantity of

hazardous waste in off-site shipments, as well as the identities of the transporters and waste receiving facilities that will manage the waste. The regulations require waste handlers to sign the manifest form by hand when they receive a waste shipment, and to retain copies of the signed manifests that document the chain of custody of a shipment, and any discrepancies.

EPA and DOT have authority to eliminate variability among State manifests, since DOT's hazardous materials laws generally call for uniformity in the use of hazardous materials shipping papers such as the manifest, and EPA must regulate transportation consistently with DOT. EPA and DOT consented in 1984 to the inclusion of several "optional" data fields, but our experience with the manifest system has demonstrated that the inclusion of optional fields introduces excessive variability and burden for waste handlers. EPA also has authority to automate the waste tracking functions of the manifest, since the Act states that EPA can employ any reasonable means necessary to track waste shipments under a manifest system. There is nothing in the statute that precludes EPA from establishing standards allowing electronic manifesting of shipments, as well as use of the traditional paper forms.

#### Alternatives:

The form revisions part of the rulemaking examines alternatives to the current system that allows authorized States to print and distribute slightly varying manifest forms (typically for a fee) to waste handlers generating or shipping waste in a particular State. This rule would establish a precise Federal specification for the manifest that would preclude variability in manifest forms, wherever they are used. This option was proposed in May 2001, and was supported by the great preponderance of commenters who submitted written comments to the docket.

The rule also examines alternative electronic formats for completing electronic manifests, and alternative methods for signing manifests electronically. Moreover, EPA has been examining in response to comments whether electronic manifest systems should be developed in a decentralized fashion by private companies in adherence with standards announced by EPA (the proposed approach), or developed and hosted centrally in a national system. We expect that additional stakeholder outreach will be

necessary to determine the appropriate design and functionality of the e-manifest approach for the final rule. Therefore, the e-manifest part of the rulemaking has been separated from the form revisions part of the rule, so that final action on the form revisions will not be delayed by future outreach and analysis conducted in connection with the e-manifest.

#### Anticipated Cost and Benefits:

The baseline manifest system results in annual paperwork burdens of 4.6 million hours and annual costs of about \$193 million. In developing the May 2001, proposed rule, EPA estimated that the proposed revisions to the hazardous waste manifest system (form changes and electronic manifest) would reduce the paperwork burdens imposed by the manifest by 765,000 to 1.24 million hours annually, and would reduce annual costs by \$24 to \$37 million. The rule should also eliminate much of the complexity that arises from having to obtain and comply with States' slightly varying manifest forms, and the burden and complexity of having to supply information to satisfy the current so-called "optional" State fields. The ability to complete and transmit manifest data electronically should improve the accuracy of manifest data, and the timeliness and effectiveness of waste shipment tracking.

#### Risks:

This rule addresses only administrative requirements for tracking waste shipments. The rule does not address risks posed by particular substances or waste management activities, and no risk assessments have been prepared to support this action.

#### Timetable:

Action	Date	FR Cite
NPRM	05/22/01	66 FR 28240
Final Action	01/00/05	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

No

#### Government Levels Affected:

Federal, State

#### Additional Information:

SAN No. 3147, EDocket No. RCRA-2001-0032; Because of significant issues identified during the public comment period on the electronic manifest part of the rule, this part of the rule has

been separated from the form revisions part of the rule for purposes of publishing a final action. The form revisions part of the rule will be finalized first.

#### Sectors Affected:

325 Chemical Manufacturing; 2211 Electric Power Generation, Transmission and Distribution; 332 Fabricated Metal Product Manufacturing; 2122 Metal Ore Mining; 2111 Oil and Gas Extraction; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 323 Printing and Related Support Activities; 3221 Pulp, Paper, and Paperboard Mills; 482 Rail Transportation; 484 Truck Transportation; 5621 Waste Collection; 5622 Waste Treatment and Disposal; 483 Water Transportation

#### URL For More Information:

<http://www.epa.gov/epaoswer/hazwaste/gener/manifest/index.htm>

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RIN: 2050-AE21

#### EPA

#### 133. STANDARDIZED PERMIT FOR RCRA HAZARDOUS WASTE MANAGEMENT FACILITIES

#### Priority:

Other Significant

#### Legal Authority:

42 USC 6905; 42 USC 6912; 42 USC 6924; 42 USC 6925; 42 USC 6927; 42 USC 6974

#### CFR Citation:

40 CFR 124; 40 CFR 267; 40 CFR 270

#### Legal Deadline:

None

**Abstract:**

EPA has proposed creating a new type of general permit, called a standardized permit, for facilities that generate waste and routinely manage the waste on-site in tanks, containers, and containment buildings. Under the standardized permit, facility owners and operators would certify compliance with generic design and operating conditions set on a national basis. The permitting agency would review the certifications submitted by the facility owners and operators. The permitting agency would also be able to impose additional site-specific terms and conditions for corrective action or other purposes, as called for by RCRA. Ensuring compliance with the standardized permit's terms and conditions would occur during inspection of the facility after the permit has been issued. The standardized permit should streamline the permit process by allowing facilities to obtain and modify permits more easily while maintaining the protectiveness currently existing in the individual RCRA permit process. EPA estimates that the potential average annual cost savings to eligible facilities from implementation of this rule will range from approximately \$100 to \$5,800 (i.e., 2 to 140 burden hours) per permit action, depending on such things as the type of permit and the type of storage equipment. The proposal raised issues for public comment on how all facilities receiving RCRA permits can satisfy RCRA corrective action requirements under appropriate alternative State cleanup programs and on financial assurance issues. The Agency is developing a final rule addressing this topic.

**Statement of Need:**

The Agency convened a special task force in 1994 to look at permitting activities throughout its different programs and to make specific recommendations to improve these permitting programs. This task force, known as the Permits Improvement Team (PIT), spent two years working with stakeholders from the Agency, State permitting agencies, industry, and the environmental community. The PIT stakeholders mentioned, among other things, that permitting activities should be commensurate with the complexity of the activity. The stakeholders felt that current Agency permitting programs were not flexible enough to allow streamlined procedures for routine permitting activities. Currently, facilities that store, treat, or dispose of hazardous waste must obtain site-specific "individual" permits

prescribing conditions for each "unit" (e.g., tank, container area, etc.) in which hazardous waste is managed. Experience gained by the Agency and States over the past 15 years has shown that not all the waste management activities are at the same level of complexity. Some activities, such as thermal treatment or land disposal of hazardous wastes, are more complex than storage of hazardous waste. The Agency believes that thermal treatment and land disposal activities continue to warrant "individual" permits, prescribing unit-specific conditions. However, the Agency believes that some accommodation can be made for hazardous waste management practices in standardized units such as tanks, container storage areas, and containment buildings. In April 1996, the PIT tentatively recommended, among other things, that regulations be developed to allow "standardized permits" for on-site storage and non-thermal treatment of hazardous waste in tanks, containers, and containment buildings. On October 12, 2001, the Agency proposed revising the RCRA regulations to allow for this type of permit, and is preparing to finalize the rule.

**Summary of Legal Basis:**

Facilities that manage hazardous waste are required under RCRA to obtain a permit and carry out corrective action as necessary (see: RCRA sections 3004, 3005, 3008, and 3010). EPA has discretion under these statutory provisions to apply different permitting procedures to different types of facilities. No aspect of this streamlining action is required by court order.

**Alternatives:**

EPA considered several options regarding RCRA permits and corrective action alternatives. The Agency proposed to limit the scope of the rule to facilities that generate waste and manage it on-site, but asked for comment on whether to expand that scope to facilities that manage wastes generated off-site. The Agency also asked for comment on the option of allowing a facility's RCRA corrective action activities to be postponed if corrective action is being carried out under an approved State remedial program.

**Anticipated Cost and Benefits:**

The RCRA standardized permit is an optional rule designed to streamline the regulatory burden to EPA/States, as well as to private sector facilities covered by the rule, by reducing the

amount of information collected, submitted, and reviewed for RCRA hazardous waste permit actions (i.e., new permit applications, permit modifications, and permit renewals). Because the rule proposed to streamline existing RCRA regulation, rather than add new RCRA regulation, implementation of the rule by the EPA and by States with EPA-authorized permitting programs is expected to result in economic benefits in the form of national cost savings from reducing both government and private sector resources required for the RCRA permit process. The national workload level of RCRA permit actions involving on-site hazardous waste storage and non-thermal treatment units has averaged 92 permit determinations per year over the 10-year period 1990-1999. Relative to this average annual workload, EPA estimates that the potential average annual cost savings to eligible facilities from implementation of this rule will range from approximately \$100 to \$5,800 (i.e., 2 to 140 burden hours) per permit action, depending on such things as the type of permit and the type of storage equipment. On a national basis, the rule is expected to generate a minimum of \$0.36 to \$0.53 million in average annual paperwork cost savings, based on the scope of the proposed rule, which was limited to on-site waste management facilities. However, the final rule may expand the initial scope of eligible facilities, which could easily double or triple the national cost savings benefits (i.e., \$1.1 to \$1.6 million per year in cost savings).

**Risks:**

The purpose of this rule is to streamline existing RCRA permit application and issuance procedures to achieve national paperwork burden reduction. Because of the facts that facilities covered by this rule: (a) Are currently already required to obtain RCRA permits, and (b) are relatively simple to design, install/construct, operate, and clean-close, this rule is expected to have minimal incremental effects on existing levels of human health and environmental risk for these types of hazardous waste management facilities.

**Timetable:**

Action	Date	FR Cite
NPRM	10/12/01	66 FR 52192
Final Action	04/00/05	

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

Federal, State

**Additional Information:**

SAN No. 4028;

**Sectors Affected:**

3251 Basic Chemical Manufacturing; 332813 Electroplating, Plating, Polishing, Anodizing and Coloring; 32551 Paint and Coating Manufacturing; 32532 Pesticide and Other Agricultural Chemical Manufacturing; 32411 Petroleum Refineries; 325211 Plastics Material and Resin Manufacturing; 3252 Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing

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RIN: 2050-AE44

**EPA****134. RCRA BURDEN REDUCTION INITIATIVE****Priority:**

Other Significant

**Legal Authority:**

42 USC 6907; 42 USC 6912(a); 42 USC 6921; 42 USC 6922; 42 USC 6923; 42 USC 6924; 42 USC 6925; 42 USC 6926; 42 USC 6927; 42 USC 6930; 42 USC 6934; 42 USC 6935; 42 USC 6937; 42 USC 6938; 42 USC 6939; 42 USC 6944; 42 USC 6949(a); 42 USC 6974; PL 104-13

**CFR Citation:**

40 CFR 261.38; 40 CFR 264.16; 40 CFR 264.52; 40 CFR 264.56; 40 CFR 264.73; 40 CFR 264.98 et seq; 40 CFR 265.16; 40 CFR 265.52; 40 CFR 265.56; 40 CFR 265.73; 40 CFR 265.98 et seq; 40 CFR 266.103; 40 CFR 261.4; 40 CFR 268.7; 40 CFR 268.9

**Legal Deadline:**

None

**Abstract:**

EPA plans to reduce the burden imposed by the RCRA reporting and

recordkeeping requirements to help meet the Federal Governmentwide goal established by the Paperwork Reduction Act (PRA).

In June 1999, EPA published a Notice of Data Availability (NODA) in the Federal Register (64 FR 32859) to seek comment on a number of burden reduction ideas to eliminate duplicative and nonessential paperwork. After reviewing the comments received on the NODA, EPA proposed (67 FR 2518, 1/17/02) to implement many of these ideas. EPA issued a notice (68 FR 61662; 10/29/03) seeking further input on a number of changes we proposed. EPA plans to finalize this burden reduction effort.

**Statement of Need:**

The Paperwork Reduction Act of 1995 establishes a Federal Governmentwide goal to reduce the paperwork and reporting burden it imposes. The RCRA Burden Reduction Initiative Proposed Rulemaking makes the regulatory changes necessary to meet this goal.

**Summary of Legal Basis:**

This action is not required by statute or court order.

**Alternatives:**

Reducing recordkeeping and reporting will require changes in our regulations. There was no alternative to doing a rulemaking. The Agency sought opinions from the regulated community on various burden reduction possibilities.

**Anticipated Cost and Benefits:**

Our cost-benefit analysis showed a savings of \$120 million and 929,000 hours for the final rule. The rule will have minimal impact on the protectiveness of the RCRA regulations. It will eliminate or streamline paperwork requirements that are unnecessary because they add little to the protectiveness of the RCRA regulations.

**Risks:**

The rule will have no risk impacts.

**Timetable:**

Action	Date	FR Cite
NODA 1	06/18/99	64 FR 32859
NPRM	01/17/02	67 FR 2518
NODA 2	10/29/03	68 FR 61662
Final Action	08/00/05	

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

Federal, Local, State, Tribal

**Additional Information:**

SAN No. 4084; Applicable SIC codes: Chemicals and Allied Products (28), Primary Metal Industries (33), Fabricated Metals (34), Industrial Machinery and Equipment (35), Electrical Equipment (36), Transportation Equipment (37), Other Manufacturing, Transportation and Utilities (40-49), Wholesale Trade (50-51), Services (70-89) and Other SIC Groups

**Sectors Affected:**

325 Chemical Manufacturing; 334 Computer and Electronic Product Manufacturing; 332 Fabricated Metal Product Manufacturing; 324 Petroleum and Coal Products Manufacturing; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 323 Printing and Related Support Activities; 562 Waste Management and Remediation Services

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RIN: 2050-AE50

**EPA****135. RECYCLING OF CATHODE RAY TUBES (CRTS): CHANGES TO HAZARDOUS WASTE REGULATIONS****Priority:**

Other Significant

**Legal Authority:**

42 USC 6912(a); 42 USC 6921; 42 USC 6922; 42 USC 6923; 42 USC 6924; 42 USC 6925

**CFR Citation:**

40 CFR 261; 40 CFR 273

**Legal Deadline:**

None

**Abstract:**

This action will ultimately revise the existing Federal hazardous waste regulations to encourage recycling and better management of Cathode Ray



Tubes (CRTs) by providing a conditional exclusion from the definition of solid waste for CRTs being recycled. A CRT is the display component of a television or computer monitor. A CRT is made largely of specialized glasses, some of which contain lead to protect the user from X-rays inside the CRT. Due to the lead, when they are disposed of or reclaimed, some CRTs are hazardous wastes under the Federal Resource Conservation and Recovery Act (RCRA) regulations.

**Statement of Need:**

This rule is needed to respond to recommendations of the Electronics Subcommittee of the CSI Council regarding CRT recycling. It is also needed to streamline RCRA requirements for these materials to encourage better management and recycling.

**Summary of Legal Basis:**

This action is not required by statute or court order.

**Alternatives:**

EPA solicited comments on alternative management requirements, including notification and tracking, accumulation requirements, requirements for CRT glass processors, export requirements, and disposal requirements.

**Anticipated Cost and Benefits:**

EPA estimates that, if finalized, this action would result in annual savings of up to 3 million dollars to reduce administrative, transportation, and management costs compared to current regulations.

**Risks:**

The risks are undetermined.

**Timetable:**

Action	Date	FR Cite
NPRM	06/12/02	67 FR 40507
Final Action	08/00/05	

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

Federal, Local, State, Tribal

**Additional Information:**

SAN No. 4092, EDocket No. RCRA-2004-0010 (CRTs) RCRA-2004-0012 (Mercury devices);

**Sectors Affected:**

334411 Electron Tube Manufacturing

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RIN: 2050-AE52

**EPA****136. • HAZARDOUS WASTE MANAGEMENT SYSTEM; MODIFICATION OF THE HAZARDOUS WASTE PROGRAM: MERCURY-CONTAINING EQUIPMENT****Priority:**

Other Significant

**Legal Authority:**

42 USC 6912(a); 42 USC 6921; 42 USC 6922; 42 USC 6923; 42 USC 6924; 42 USC 6925

**CFR Citation:**

40 CFR 261; 40 CFR 273

**Legal Deadline:**

None

**Abstract:**

Mercury-containing equipment (MCE) consists of devices, items, or articles that contain varying amounts of elemental mercury that is integral to their functions, including several types of instruments that are used throughout the electric utility industry and other industries, municipalities, and households. Some commonly recognized devices are thermostats, barometers, manometers, and mercury switches, such as light switches in automobiles. This definition does not include mercury waste that is generated as a byproduct through the process of manufacturing or treatment. This action will add mercury-containing equipment to the federal list of universal wastes regulated under the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. Handlers of universal wastes are subject to less stringent standards for storing, transporting, and collecting these wastes. EPA believes that regulating spent mercury-containing equipment as a universal waste will lead to better management of this equipment and will facilitate compliance with hazardous waste requirements.

**Statement of Need:**

This rule is needed to respond to a petition from the Utilities Solid Waste Activities Group regarding management of mercury-containing equipment. It is also needed to streamline RCRA requirements for these materials to encourage better management and recycling and to reduce management of mercury in the municipal waste system.

**Summary of Legal Basis:**

This action is not required by statute or court order.

**Alternatives:**

EPA solicited comments on alternative management requirements and alternative approaches for meeting its goals with respect to mercury equipment management.

**Anticipated Cost and Benefits:**

EPA estimates that, if finalized, this action would result in annual savings of up to \$270,000 to reduce administrative, transportation, and management costs compared to current regulations. In addition, this action would improve management of mercury wastes from small and large generators and increase collection of these materials for proper management.

**Timetable:**

Action	Date	FR Cite
Final Action	06/00/05	

**Regulatory Flexibility Analysis Required:**

DATA MISSING

**Government Levels Affected:**

Federal, Local, State, Tribal

**Additional Information:**

SAN No. 4092.1, EDocket No. RCRA-2004-0010 (CRTs) RCRA-2004-0012 (Mercury devices); Split from RIN 2050-AE52.

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RIN: 2050-AG21

**EPA****137. NATIONAL PRIMARY DRINKING WATER REGULATIONS: GROUNDWATER RULE****Priority:**

Economically Significant. Major under 5 USC 801.

**Unfunded Mandates:**

This action may affect the private sector under PL 104-4.

**Legal Authority:**

42 USC 300 g-1 SDWA 1412 (b)(8); 42 USC 300j-4 SDWA 1445

**CFR Citation:**

40 CFR 141; 40 CFR 142

**Legal Deadline:**

Other, Statutory, Not later than promulgation of the Stage 2 Disinfection Byproducts Rule (currently scheduled for July 2005).

**Abstract:**

EPA has proposed a targeted risk-based regulatory strategy for all public water systems served by groundwater. The proposed requirements provide a meaningful opportunity to reduce public health risk for a significant number of people served by groundwater sources from the exposure to waterborne pathogens from fecal contamination. The proposed strategy addresses risks through a multiple-barrier approach that relies on five major components: periodic sanitary surveys of groundwater systems requiring the evaluation of eight elements and the identification of significant deficiencies; hydrogeologic assessments to identify wells sensitive to fecal contamination; source water monitoring for systems drawing from sensitive wells without treatment or with other indications of risk; a requirement for correction of significant deficiencies and fecal contamination through the following actions: eliminate the source of contamination, correct the significant deficiency, provide an alternative source water, or provide a treatment which achieves at least 99.99 percent (4-log) inactivation or removal of viruses; and compliance monitoring to insure disinfection treatment is reliably operated where it is used.

**Statement of Need:**

Public water systems (PWSs) that use groundwater as their sole source of water, as opposed to surface water PWSs, are not federally regulated as to treatment for microorganisms. There is data that indicates that a number of

groundwater PWSs are contaminated with microorganisms of fecal origin that can and have caused illness.

**Summary of Legal Basis:**

Section 1412(b)(8) of the Safe Drinking Water Act requires that EPA develop regulations specifying the use of disinfectants for ground water systems as necessary and "... (as part of the regulations) promulgate criteria... to determine whether disinfection shall be required as a treatment technique for any public water system served by ground water."

**Alternatives:**

EPA considered four regulatory alternatives in the development of the GWR proposal; the proposed regulatory alternative (multi-barrier option), the sanitary survey option, the sanitary survey and triggered monitoring option, and the across-the-board disinfection option. All options include the sanitary survey provision. The sanitary survey option would require the primacy agency to perform surveys every three to five years, depending on the type of system. If any significant deficiency is identified, a system is required to correct it. The sanitary survey and triggered monitoring option adds a source water fecal indicator monitoring requirement triggered by a total coliform positive sample in the distribution system. The multi-barrier option, which was proposed by EPA, adds a hydrogeologic sensitivity assessment to these elements which, if a system is found to be sensitive, results in a routine source water fecal indicator monitoring requirement. The multi-barrier option and the sanitary survey and triggered monitoring options are targeted regulatory approaches designed to identify wells that are fecally contaminated or are at a high risk for contamination. The across-the-board disinfection option would require all systems to install treatment instead of trying to identify only the high risk systems; therefore, it has no requirement for sensitivity assessment or microbial monitoring.

**Anticipated Cost and Benefits:**

EPA estimates the cost of the proposed GWR will be \$183 million dollars per year (using a 3 percent discount rate). More than half of the estimated costs are for corrective actions which systems will be required to take to fix or prevent fecal contamination. The remainder of the costs are due to increased scope and frequency of sanitary surveys, hydrogeologic sensitivity assessments and source

water monitoring. System costs are expected to be \$162 million per year for implementation of the GWR. States are expected to incur costs of \$21 million per year. Cost estimates do not include land acquisition, public notification or the potential cost of illness due to exposure to disinfection by-products. The total estimated value of these benefits is \$205 million per year, \$139 million from avoided illness and \$66 million from avoided deaths. These benefits are monetized based on a cost of illness and a value of statistical life. These estimates do not include pain and suffering associated with viral and bacterial illness avoided outbreak response costs (such as the costs of providing public health warnings and boiling drinking water), and possibly the avoided costs of averting behavior and reduced uncertainty about drinking water quality.

**Risks:**

EPA estimates that currently over 200,000 illnesses and 18 deaths occur each year due to viral and bacterial contamination of public groundwater systems. Children, the elderly and the immunocompromised are particularly sensitive to the waterborne pathogens and account for between 20 and 30 percent of the illnesses and deaths. As proposed, the GWR is expected to reduce the total number of illnesses by 115,000 and the total number of deaths by 11 each year. The GWR in conjunction with the Surface Water Treatment Rule (SWTR), Total Coliform Rule (TCR) the Interim Enhanced Surface Water Treatment Rule (IESWTR), the Filter Backwash Rule (FBR) and the Long Term Enhanced Surface Water Treatment Rules (LT1ESWTR and LT2ESWTR) will provide protections to the consumers of public water supply systems from waterborne pathogens.

**Timetable:**

Action	Date	FR Cite
NPRM	05/10/00	65 FR 30194
Final Action	05/00/05	

**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Federal, Local, State, Tribal

**Additional Information:**

SAN No. 2340; Statutory deadline for final rule: After August 6, 1999, but not later than the Administrator promulgates a Stage II rulemaking for disinfection byproducts (currently scheduled for July 2005).

**Sectors Affected:**

22131 Water Supply and Irrigation Systems

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**RIN:** 2040-AA97

**EPA****138. NATIONAL PRIMARY DRINKING WATER REGULATIONS: LONG TERM 2 ENHANCED SURFACE WATER TREATMENT RULE****Priority:**

Economically Significant. Major under 5 USC 801.

**Unfunded Mandates:**

This action may affect State, local or tribal governments and the private sector.

**Legal Authority:**

42 USC 300f; 42 USC 300g-1; 42 USC 300g-2; 42 USC 300g-3; 42 USC 300g-4; 42 USC 300g-5; 42 USC 300g-6; 42 USC 300j-4; 42 USC 300j-9; 42 USC 300j-11

**CFR Citation:**

40 CFR 141 to 142; 40 CFR 9

**Legal Deadline:**

None

**Abstract:**

The Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) will control risk from microbial pathogens, specifically cryptosporidium, in drinking water. It

is being developed simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR), which will address risk caused by the use of disinfectants in drinking water. This rule could affect all public water systems that use surface water as a source. Promulgating the LT2ESWTR and the Stage 2 DBPR as a paired rulemaking is necessary to ensure that adequate protection from microbial risk is maintained while EPA manages risk from disinfection byproducts. In developing the LT2ESWTR, EPA has analyzed a significant body of new survey data on microbial pathogens in source and finished waters, as well as data on parameters which could serve as indicators of microbial risk. This survey data, which was collected under the Information Collection Rule (ICR), Supplemental Surveys to the ICR, and additional research projects, has provided a substantially more comprehensive and complete picture of the occurrence of waterborne pathogens than was previously available. EPA has also used significant new data on the efficiency of treatment processes for the removal and inactivation of microorganisms, as well as new information on the pathogenicity of certain microbes, to determine effective regulatory requirements for controlling microbial risk. On March 30, 1999, EPA established a committee of stakeholders under the Federal Advisory Committee Act (FACA) to assist in the development of these rules; an agreement in principle was signed in September 2000 outlining the proposed rule options.

**Statement of Need:**

The purpose of the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) is to reduce health risks posed by Cryptosporidium and other microbial pathogens in drinking water. Cryptosporidium is a protozoa which causes cryptosporidiosis, a severe gastrointestinal disease. While cryptosporidiosis is generally self limiting in healthy individuals, it can be fatal for people with compromised immune systems. Cryptosporidium is removed to a degree by filtration but is highly resistant to conventional drinking water disinfectants, including chlorine and chloramines. EPA has recently collected a significant amount of data on occurrence of Cryptosporidium in drinking water sources through the Information Collection Rule (ICR) and ICR Supplemental Surveys. These data indicate that a subset of drinking water systems have an unacceptably high risk

for Cryptosporidium in their treated water. The LT2ESWTR is intended to identify systems at high risk for Cryptosporidium through monitoring and prescribe an appropriate level of additional treatment. In addition, the LT2ESWTR will be promulgated simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR). This will help to ensure that drinking water utilities do not compromise adequate microbial protection while they take steps to control DBPs.

**Summary of Legal Basis:**

Section 1412(b)(7)(A) of SDWA authorizes the Administrator to promulgate a national primary drinking water regulation that requires the use of a treatment technique in establishing a maximum contaminant level if the Administrator makes a finding that it is not feasible to ascertain the level of the contaminant. The MCLG for Cryptosporidium is zero and it is not feasible for public water systems to measure Cryptosporidium concentrations in treated water. Consequently, under Section 1412(b)(1)(A), the Administrator may establish a treatment technique for Cryptosporidium if this presents a meaningful opportunity for health risk reduction. Although the 1996 Amendments do not require EPA to finalize a Long Term 2 Enhanced Surface Water Treatment Rule concurrently with the Stage 2 Disinfectants and Disinfection Byproducts Rule, Congress did emphasize the importance of ensuring proper balance between microbial and DBP risks and, therefore, EPA believes it is important to finalize these rules together.

**Alternatives:**

EPA is considering various rule scenarios to reduce risk from Cryptosporidium. These scenarios include treatment requirements that would apply to all systems, such as requiring all conventional plants to achieve 2-log inactivation of Cryptosporidium. Alternative scenarios have involved assigning systems to bins based on mean Crypto source water concentrations. Additional treatment requirements would then depend on the bin to which a system was assigned. Issues associated with the binning approach include: amount of monitoring necessary to assign systems to bins, appropriate Crypto concentrations to demarcate bin boundaries, and appropriate level of additional treatment for a given bin.

EPA is exploring analyses that evaluate the impact of these issues on costs and benefits. EPA has also considered options to reduce the impact on small systems.

#### Anticipated Cost and Benefits:

EPA estimates that the LT2ESWTR, as proposed will have an annual cost of \$73 to \$111 million per year. The majority of people (approximately 67 percent) are served by public water systems that use a surface water or ground water under the direct influence of surface water. Thus, a large number of people will benefit from the LT2ESWTR. EPA estimates that the proposed LT2ESWTR would prevent up to 1,020,000 cases of cryptosporidiosis annually with an economic benefit of up to \$1.4 billion. In addition, EPA has recently identified UV light as a technology that can achieve high levels of Cryptosporidium inactivation at relatively low cost.

#### Risks:

Approximately 67 percent of consumers are served by drinking water systems that use surface water sources or ground water under the direct influence of surface water. Survey data indicate that Cryptosporidium is prevalent in drinking water sources and current levels of treatment may not be adequate to control highly resistant pathogens like Cryptosporidium.

Cryptosporidiosis is a potentially fatal disease in people with weak immune systems, such as infants, the elderly, people with AIDS, and people taking immune suppressing drugs like cancer and transplant patients. By requiring additional treatment for those systems with the highest concentrations of Cryptosporidium in their source waters, EPA expects to significantly reduce current risk.

#### Timetable:

Action	Date	FR Cite
NPRM	08/11/03	68 FR 47639
Final Action	07/00/05	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

Businesses

#### Government Levels Affected:

Federal, Local, State, Tribal

#### Federalism:

This action may have federalism implications as defined in EO 13132.

#### Additional Information:

SAN 4341.

#### Sectors Affected:

22131 Water Supply and Irrigation Systems

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RIN: 2040-AD37

#### EPA

### 139. NATIONAL PRIMARY DRINKING WATER REGULATIONS: STAGE 2 DISINFECTION BYPRODUCTS RULE

#### Priority:

Economically Significant

#### Unfunded Mandates:

This action may affect State, local or tribal governments and the private sector.

#### Legal Authority:

42 USC 300f; 42 USC 300g-2; 42 USC 300g-3; 42 USC 300g-4; 42 USC 300g-5; 42 USC 300g-6; 42 USC 300j-4; 42 USC 300j-9; 42 USC 300j-11

#### CFR Citation:

40 CFR 141 to 142; 40 CFR 9

#### Legal Deadline:

Final, Statutory, July 14, 2003.

#### Abstract:

This Regulation, along with a Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) that will be promulgated simultaneously, is intended to expand existing public health protections and address concerns about risk trade-offs between pathogens and disinfection byproducts. This rule could affect all public water systems that add a disinfectant to the drinking water during any part of the treatment process, although the impacts

may be limited to community water systems (CWSs) and non-transient non-community water systems (NTNCWSs). Promulgating the LT2ESWTR and the Stage 2 DBPR as a paired rulemaking is necessary to ensure that adequate protection from microbial risk is maintained while EPA manages risk from disinfection byproducts. In developing the Stage 2 DBPR, EPA analyzed a significant body of new survey data on source water quality parameters, treatment data and disinfection byproduct occurrence. This survey data, which was collected under the Information Collection Rule (ICR), Supplemental Surveys to the ICR, and additional research projects, provide a substantially more comprehensive and complete picture of the occurrence of DBPs and microbiological pathogens than was previously available. EPA also used new information on the health effects of exposure to DBPs to determine effective regulatory requirements for controlling risk. On March 30, 1999, EPA reconvened a committee of stakeholders under the Federal Advisory Committee Act (FACA) to assist in the development of these rules; an Agreement in Principle was signed in September 2000 outlining the proposed rule options.

#### Statement of Need:

The purpose of the Stage 2 Disinfectants/Disinfection Byproducts Rule (DBPR) is to reduce potential health risks posed by disinfection byproducts (DBPs). Certain DBPs have been shown in laboratory tests to be carcinogens or to cause adverse reproductive and developmental health effects. In addition, epidemiology studies have indicated that exposure to chlorinated water may increase the risk of bladder cancer, miscarriage, and certain developmental defects. The Stage 2 DBPR is designed to reduce peak events in DBP exposure in order to mitigate these potential health risks.

#### Summary of Legal Basis:

Section 1412(b)(2)(C) of SDWA, as amended in 1996, requires EPA to promulgate a Stage 2 Disinfectants/Disinfection Byproducts Rule no later than July 14, 2003. Although the 1996 Amendments do not require EPA to finalize a Long Term 2 Enhanced Surface Water Treatment Rule concurrently with the Stage 2 Disinfectants and Disinfection Byproducts Rule, Congress did emphasize the importance of ensuring proper balance between microbial and DBP risks and, therefore, EPA believes

it is important to finalize these rules together.

#### Alternatives:

EPA is considering various rule scenarios to achieve reductions in disinfection byproduct exposure. These alternatives include: decreasing the standard set in the Stage 1 DBPR (0.080 mg/L total trihalomethanes (TTHM) and 0.060 mg/L the sum of 5 haloacetic acids (HAA5)) by half and maintaining a running annual average compliance calculation; maintaining 80/60 TTHM/HAA5 standards but revising the compliance calculation to a stricter locational running annual average; setting the 80/60 TTHM/HAA5 standard as a never to be exceeded maximum; and revising the standard for bromate which is currently 0.010 mg/L. EPA has also considered options to reduce the impact on small systems.

#### Anticipated Cost and Benefits:

EPA estimates that the Stage 2 DBPR will have an annual economic impact of \$59-65 million. Over 200 million people are served by public water systems that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants and potentially exposed to DBPs. Thus, a large number of people will benefit from the Stage 2 DBPR.

#### Risks:

Over 200 million people are served by public water systems that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants. Due to the large number of people exposed to DBPs, there is a substantial concern for any risks associated with DBPs that may impact public health. EPA estimates that the Stage 2 DBPR will decrease exposure to DBPs on average but more importantly, the rule will significantly reduce exposure to peak occurrences of DBPs.

#### Timetable:

Action	Date	FR Cite
NPRM	08/18/03	68 FR 49548
Final Action	07/00/05	

#### Regulatory Flexibility Analysis Required:

No

#### Small Entities Affected:

Businesses

#### Government Levels Affected:

Federal, Local, State, Tribal

#### Federalism:

This action may have federalism implications as defined in EO 13132.

#### Additional Information:

SAN 4342.

#### Sectors Affected:

22131 Water Supply and Irrigation Systems

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RIN: 2040-AD38

#### EPA

#### 140. MINIMIZING ADVERSE ENVIRONMENTAL IMPACT FROM COOLING WATER INTAKE STRUCTURES AT EXISTING FACILITIES UNDER SECTION 316(B) OF THE CLEAN WATER ACT, PHASE 3

#### Priority:

Other Significant

#### Unfunded Mandates:

This action may affect the private sector under PL 104-4.

#### Legal Authority:

33 USC 1311 CWA 301; 33 USC 1316 CWA 306; 33 USC 1326 CWA 316; 33 USC 1361 CWA 501

#### CFR Citation:

40 CFR 9; 40 CFR 122; 40 CFR 123; 40 CFR 124; 40 CFR 125

#### Legal Deadline:

NPRM, Judicial, November 1, 2004.  
Final, Judicial, June 1, 2006.

#### Abstract:

This rulemaking will affect existing facilities that use cooling water intake structures, and whose intake flow levels exceed a minimum threshold to be determined by EPA during this

rulemaking. The proposed rule addresses all existing facilities if they meet the proposed threshold levels, including those in the following industries: (1) Electricity generating facilities not covered by Phase 2 regulations; (2) pulp and paper manufacturing facilities; (3) chemicals and allied products manufacturing facilities; (4) petroleum and coal products manufacturing facilities; and (5) primary metals manufacturing facilities. EPA also proposed regulations for new offshore and coastal oil and gas extraction facilities, which EPA excluded from the Phase I rule for other, land-based facilities. Section 316(b) of the Clean Water Act provides that any standard established pursuant to sections 301 or 306 of the Clean Water Act and applicable to a point source shall require that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. A primary purpose of this action is to minimize the impingement and entrainment of fish and other aquatic organisms by cooling water intake structures. Impingement occurs when fish and other aquatic life are trapped against cooling water intake structures. Entrainment occurs when aquatic organisms, eggs and larvae are drawn into a cooling system and then pumped back out, resulting in significant injury or mortality to the entrained organisms.

#### Statement of Need:

In the absence of national regulations, Permit Directors have regulated cooling water intake structures incompletely and inconsistently, especially with respect to the manufacturing sector. In some instances, permit issuance or reissuance has been significantly delayed or permit decisions from 20 or more years ago have not been reevaluated. Significant numbers of fish and other aquatic organisms may be cropped annually as a result of cooling water intake structures at a single large intake or through the cumulative impact at multiple small intakes on the same waterbody. By court order, EPA must propose and take final action on this regulation. This regulation may have substantial ecological benefits.

#### Summary of Legal Basis:

This action is required under an Amended Consent Decree in *Riverkeeper Inc. et al. v. Whitman*, 93 Civ. 0314 (AGS)(U.S. District Court, Southern District of New York, November 21, 2000).

**Alternatives:**

This analysis will cover various sizes and types of potentially regulated facilities. EPA is considering whether to regulate on a site-specific, waterbody category, or national basis. EPA is also considering several flow thresholds, below which the regulation would not apply and permits would continue to be issued on a case-by-case basis by Permit Directors using their best professional judgment.

**Anticipated Cost and Benefits:**

Costs are yet to be determined, but are not expected to exceed \$100 million. While monetized use benefits are expected to be lower than monetized costs, a qualitative assessment of ecological benefits at several large facilities indicates the potential for additional benefits when intakes are controlled. Costs and benefits are generally expected to be smaller at facilities that use smaller amounts of cooling water.

**Risks:**

Cooling water intake structures may pose significant risks for aquatic ecosystems.

**Timetable:**

Action	Date	FR Cite
NPRM	11/00/04	
Final Action	06/00/06	

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Federal, Local, State, Tribal

**Additional Information:**

SAN No. 4543; Split from RIN 2040-AC34.

**Sectors Affected:**

312 Beverage and Tobacco Product Manufacturing; 325 Chemical Manufacturing; 61131 Colleges, Universities and Professional Schools; 334 Computer and Electronic Product Manufacturing; 211111 Crude Petroleum and Natural Gas Extraction; 22111 Electric Power Generation; 335 Electrical Equipment, Appliance and Component Manufacturing; 332 Fabricated Metal Product Manufacturing; 311 Food Manufacturing; 333 Machinery Manufacturing; 21 Mining; 211112 Natural Gas Liquid Extraction; 327 Nonmetallic Mineral Product

Manufacturing; 322 Paper Manufacturing; 324 Petroleum and Coal Products Manufacturing; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 22133 Steam and Air-Conditioning Supply; 313 Textile Mills; 336 Transportation Equipment Manufacturing; 321 Wood Product Manufacturing

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**RIN:** 2040-AD70

**EPA****141. CROSS-MEDIA ELECTRONIC REPORTING (ER) AND RECORDKEEPING RULE (CROMERRR)****Priority:**

Other Significant

**Legal Authority:**

PL 104-13; PL 105-277

**CFR Citation:**

40 CFR 3 (New); 40 CFR 9 (Revision)

**Legal Deadline:**

None

**Abstract:**

As proposed, the Cross-Media Electronic Reporting (ER) and Recordkeeping Rule (CROMERRR) was intended to provide a uniform legal framework for paperless electronic reporting and recordkeeping, including electronic signature/certification, across EPA's environmental compliance programs. Based on public comment, however, EPA now plans to focus on finalizing the electronic reporting components of proposed CROMERRR, and to defer further action on the electronic recordkeeping components until a later time. Under current plans, the final electronic reporting (ER) rule will address electronic reporting by

companies regulated under all of EPA's programs: air, water, pesticides, toxic substances, wastes, and emergency response. The final rule would remove existing regulatory obstacles to electronic reporting, and it would set requirements for companies choosing to report electronically. In addition, the rule would set the conditions for allowing electronic reporting under State, tribal or local environmental programs that operate under EPA authorization. The final ER rule is intended to make electronic reporting as simple, efficient, and cost-effective as possible for regulated companies, while ensuring that a transition from paper to electronic reporting does not compromise EPA's compliance and enforcement programs. Consequently, the Agency's strategy is to impose as few specific requirements as possible, and to keep those requirements neutral with respect to technology, so the rule will pose no obstacles to adopting new technologies as they emerge. To ensure that authorized programs at the State, tribal, and local levels meet EPA's electronic reporting goals, the final ER rule would specify a set of criteria that these programs must satisfy as they initiate electronic reporting. In response to public comments, EPA is also planning to include provisions for a streamlined process for EPA to review and approve authorized program revisions or modifications to allow electronic reporting.

**Statement of Need:**

EPA is required by the Government Paperwork Elimination Act (GPEA) of 1998 to make the option of electronic reporting and recordkeeping available, where practicable, to its regulated community by 2003. To meet this deadline and comply with GPEA, EPA believes that it needs to put a new legal framework in place for electronic reporting. A final ER rule would provide for this legal framework by: (1) Removing legal obstacles to electronic reporting posed by explicit references to paper and paper-based processes in EPA regulations; and (2) assuring that electronically submitted documents will have the same legal and evidentiary force as their paper counterparts, whether the submission is directly to EPA or under an EPA-authorized program.

**Summary of Legal Basis:**

Government Paperwork Elimination Act (GPEA) of 1998. GPEA requires Federal agencies to provide, where practicable, the option of electronic reporting and

recordkeeping to their regulated communities by 2003.

**Alternatives:**

One alternative to an EPA cross-media ER rule that applies to most compliance reports under 40 CFR would be individual rulemakings by each of the program offices. EPA's past experience with program-by-program ER rulemakings has demonstrated that such an approach would be more costly and take much longer to complete. EPA also considered the use of guidance instead of rulemaking, but rejected this alternative based principally on a concern that program enforceability depends greatly on the ability to mandate a certain level of functionality for systems that will be used to receive electronic reports and other electronic documents.

**Anticipated Cost and Benefits:**

EPA received a number of comments on the assumptions used to generate the cost and benefit estimates for the electronic reporting components of proposed CROMERRR; based on this feedback, EPA decided to develop a new analysis of the costs and benefits for the final ER rule. As a part of this effort, EPA has conducted extensive follow-up interviews with commenters, reevaluated existing sources of information, and conducted new market research on ER technologies. The results have led EPA to revise certain assumptions associated with the CROMERRR proposal that bear on the ER rule's costs and benefits to regulated entities and to Federal, State, and local governments. Proposed CROMERRR had assumed that the costs and benefits of electronic reporting under authorized programs could be attributed entirely to the rule. EPA has since learned that a significant number of electronic reporting systems already operate under such programs; correspondingly, the ER

rule cannot take credit for the costs and benefits of electronic reporting in such cases, but only for the costs or benefits that result from changes that occur as a result of the rule. With respect to regulated entities, EPA has had to adjust a number of assumptions associated with electronic signature requirements, including those related to the number of registered signature-holders at each facility, and the availability of acceptable alternatives to Public Key Infrastructure-based electronic signature approaches in many instances. EPA is also refining its estimate of the number of potentially affected regulated entities. With respect to the Federal government, EPA has reconsidered the general costs and benefits of electronic reporting based on experience operating EPA's Central Data Exchange and other EPA systems, and based also on an in-depth analysis of business processes and associated costs for several major EPA programs implementing electronic reporting. Based on these and other revisions to our assumptions, EPA has developed preliminary new cost/benefit results. They indicate that regulated entities and State and local government agencies will incur modest net costs from the ER rule; EPA will experience modest net benefits. Qualitative benefits of electronic reporting were also identified, including: enhanced data quality, faster public access to submitted data, better tracking of compliance submissions, and opportunities for re-engineering current paper processes. Finally, comments on the CROMERRR also indicated the need for substantial reworking of the cost and benefit analyses with respect to the electronic recordkeeping components of the proposal. Given EPA's current focus on electronic reporting, EPA will defer additional economic analysis in this area until the Agency resumes work on electronic recordkeeping.

**Risks:**

The risks are undetermined.

**Timetable:**

Action	Date	FR Cite
NPRM	08/31/01	66 FR 46162
Final Action	12/00/04	

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

Federal, Local, State, Tribal

**Federalism:**

This action may have federalism implications as defined in EO 13132.

**Additional Information:**

SAN No. 4270; Formerly listed as RIN 2020-AA41.

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**RIN:** 2025-AA07

**BILLING CODE** 6560-50-S